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ERC2009-01

Evaluation Report

Mandipropamid Technical Fungicide

(publié aussi en français)

30 June 2009

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

HC Pub: 8162

ISBN: 978-1-100-12200-7 (978-1-100-12201-4)

Catalogue number: H113-26/2009-1E (H113-26/2009-1E-PDF)

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Overview

Registration Decision for Mandipropamid Technical Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of mandipropamid and Revus Fungicide containing the technical grade active ingredient Mandipropamid Technical Fungicide to control downy mildew on Brassica crops, bulb vegetables, grapes, leafy vegetables (including field and greenhouse, not for transplants for the field, and spinach); blue mould on spinach; late blight on tomatoes (including field and greenhouse, not transplants for the field), tomatillos and potatoes; suppression of phytophthora blight on peppers (Bell and non-Bell peppers to be treated in the greenhouse and immediately transplanted to the field) and suppression of downy mildew on cucurbits (including field and greenhouse, not transplants for the field).

Current scientific data from the applicant were evaluated to determine whether, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This report summarizes the information that was evaluated and provides the results of the evaluation as well as the reasons for the registration decision, with an outline of the additional scientific information required from the applicant. It also describes the conditions of registration that the applicant must meet to ensure that the health and environmental risks as well as the value of these pest control products are acceptable for their intended use.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Mandipropamid Technical Fungicide and Revus Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by Subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, and on the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Revus Fungicide?

Mandipropamid is a Group 40 fungicide active ingredient and is classified as a carboxylic acid amide. It has a proposed mode of action that inhibits phospholipid biosynthesis, and interferes with cell wall division. It is rated as having a low to medium risk for resistance development in pathogen populations. It is the active ingredient in the end-use product Revus Fungicide, which is used to control or suppress various foliar diseases when applied at rates between 400–600 mL/ha (100–150 g a.i./ha). Revus Fungicide is applied as a drench or foliar spray and can be tank mixed with Bravo 500 Agricultural Fungicide (Reg. No. 15723) for resistance management purposes, or to increase the disease spectrum for crops already registered on the Bravo 500 Agricultural Fungicide label. Revus Fungicide can be applied to field or selected greenhouse crops via ground or aerial application equipment.

Diseases controlled include downy mildew on brassica crops, bulb vegetables, grapes, leafy vegetables (including field and greenhouse, not for transplants for the field, and blue mould on spinach); late blight on tomatoes (including field and greenhouse, not transplants for the field), tomatillos and potatoes; and suppression of phytophthora blight on peppers (Bell and non-Bell peppers to be treated in the greenhouse and immediately transplanted to the field), and suppression of downy mildew on cucurbits (including field and greenhouse, not transplants for the field).

Health Considerations

Can Approved Uses of Mandipropamid Technical Fungicide Affect Human Health?

Mandipropamid Technical Fungicide is unlikely to affect your health when used according to the label directions.

Potential exposure to mandipropamid may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may

be exposed. The dose levels used to assess risks are established to protect the most sensitive human population group (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when mandipropamid products are used according to the label directions.

Mandipropamid Technical Fungicide and the end-use product, Revus Fungicide, are not acutely toxic. Consequently, no label statements are required.

Mandipropamid did not cause cancer in animals and was not genotoxic. There was also no indication that mandipropamid caused damage to the nervous system and there were no effects on reproduction or fetal development. The first signs of toxicity in animals given daily doses of mandipropamid over longer periods of time were decreases in body-weight gain and liver effects. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that would ingest the most mandipropamid relative to body weight, are expected to be exposed to less than 4.2% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from mandipropamid is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of mandipropamid is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using mandipropamid on Brassica vegetables, cucurbits, dry bulb and green onion, fruiting vegetables, grapes, leafy vegetables and potato were acceptable. Residue trials conducted in Europe using

mandipropamid on greenhouse vegetables (cucumber, lettuce and tomato) were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this Evaluation Document

Occupational Risks From Handling Revus Fungicide

Occupational risks are not of concern when Revus Fungicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Revus Fungicide, as well as field workers re-entering freshly treated fields, nurseries and greenhouses, can come in direct contact with mandipropamid residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Revus Fungicide must wear a long sleeved shirt, long pants, and shoes plus socks. Additionally, workers must wear chemical-resistant gloves during mixing/loading. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications, and the exposure duration for handlers and workers, risk to these workers is not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Mandipropamid Technical Fungicide Is Introduced Into the Environment?

When used according to the label directions, which include precautionary statements, Revus Fungicide (active ingredient mandipropamid) does not pose a risk to the environment.

Mandipropamid enters the environment when used on various crops for treatment of fungal infection. In the terrestrial environment, mandipropamid is slightly to moderately persistent with the main route of dissipation being biotransformation in soil. Mandipropamid is not expected to volatilize nor leach significantly. No major transformation products of mandipropamid were identified in the soil laboratory studies.

Mandipropamid can enter the aquatic environment through spray drift and runoff from the application field. Based on the environmental fate characteristics, limited runoff of mandipropamid and its transformation products is expected. Mandipropamid dissipates rapidly from the water layer mainly via partitioning to the sediments, but phototransformation will also contribute to this dissipation in the photic zone. Biotransformation is the main route of dissipation for mandipropamid in sediments. Mandipropamid is stable to hydrolysis and is not expected to volatilize; therefore, these two processes will not affect the dissipation of mandipropamid from the aquatic

environment. In the total aquatic system, mandipropamid is classified as non-persistent to slightly persistent depending on the system and conditions present.

Major transformation products of mandipropamid were identified in the aquatic fate studies. These transformation products will only form in significant levels in the aquatic environment if large quantities of mandipropamid enter the aquatic environment as they are not expected to be present in runoff. Further discussion regarding these transformation products occurs in the Science Evaluation section of this document.

The risk to the environment was assessed for mandipropamid and it was determined that negligible risk exists to the terrestrial and aquatic organism groups assessed from the proposed uses.

Value Considerations

What Is the Value of Revus Fungicide?

Mandipropamid, the active ingredient in Revus Fungicide, controls or suppresses downy mildew, late blight and phytophthora blight on various field and greenhouse-grown crops

Revus Fungicide is a reduced-risk product that offers a new fungicide chemistry to Canadian growers for use on leafy vegetables, grapes, tomatoes, cucurbits, bulb vegetables, and Brassica head and stem crops. It is also currently the only fungicide registered in Canada for suppression of phytophthora blight on field peppers. Revus Fungicide can be tank mixed with Bravo 500 Agricultural Fungicide for resistance management, or to increase the disease spectrum on crops that are registered on both product labels. In addition, Revus Fungicide can be applied by ground and aerial application equipment.

Sensitivity monitoring studies have suggested that populations of *Phytophthora infestans*, the causative pathogen of potato late blight, have not developed resistance to mandipropamid. However, certain isolates of *Plasmopara viticola*, the causative pathogen for downy mildew of grape, have been found to be simultaneously resistant to all Group 40 active ingredients. Therefore, resistance management practices are required when using Revus Fungicide on grapes for control of downy mildew and are highly recommended when using Revus Fungicide on other labelled crops.

Measures to Minimize Risk

The labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Revus Fungicide to address the potential risks identified in this assessment are as follows.

Human Health

Given there is a concern with users coming into direct contact with Revus Fungicide on their skin or through inhalation of spray mists, anyone mixing, loading or applying Revus Fungicide must wear a long-sleeved shirt, long pants, and shoes plus socks. Additionally, workers must wear chemical-resistant gloves during mixing/loading. In addition, standard label statements to protect against drift during application have been added to the label.

What Additional Scientific Information is Being Requested?

Although the risks and value of Mandipropamid Technical Fungicide have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

Chemistry

- Analytical data from at least five batches of the technical grade active ingredient (TGAI) representing full-scale production, once commercial production has commenced at the manufacturing site.
- Analytical methods for the transformation products of mandipropamid in water and sediment.

Human Health

- For enforcement purposes, a confirmatory method or interference study for residue analytical method (RAM) 415/01.
- Final study report demonstrating the storage stability of analytical standards.
- Freezer storage stability study for residues of SYN 500003 in potato tubers and potato processed fractions for up to 32 months of frozen storage.
- Greenhouse lettuce trials conducted according to the approved Revus Fungicide label rate.

Value

- Confirmatory efficacy trials are required to determine whether a higher rate of Revus Fungicide (150 g a.i./ha) is required for control of downy mildew (*Peronospora destructor*) on green (bunching) onions, leeks and Welch onions.
- Confirmatory efficacy trials are required that assess Revus Fungicide for control of downy mildew (*Peronospora parasitica*) on crops within the Brassica leafy greens subgroup. Efficacy data are required within two years of a conditional registration being granted.

- Confirmatory efficacy trials are required that assess Revus Fungicide for suppression of Phytophthora blight (*Phytophthora capsici*) on peppers (Bell and non-Bell), as well as all other crops within the fruiting vegetables crop group. Efficacy data are required within two years of a conditional registration being granted.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,³ the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

³ As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation

Mandipropamid Technical Fungicide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active Substance Mandipropamid

Function Fungicide

Chemical Name

1. **International Union of Pure and Applied Chemistry (IUPAC)** (RS)-2-(4-chlorophenyl)-N-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide

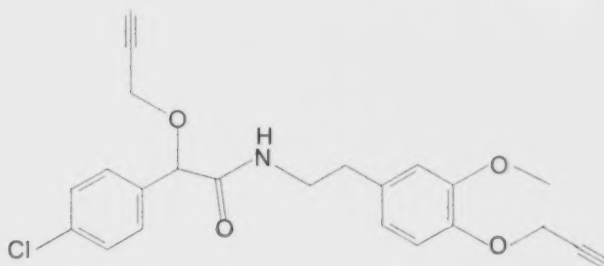
2. **Chemical Abstracts Service (CAS)** 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)benzeneacetamide

CAS Number 374726-62-2

Molecular Formula C₂₃H₂₂ClNO₄

Molecular Weight 411.9

Structural Formula



Purity of the Active Ingredient 96% nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Mandipropamid Technical Fungicide

Property	Result																
Colour and physical state	Light beige powder																
Odour	Odourless																
Melting range	96.4–97.3°C																
Boiling point	Not applicable for a solid																
Density	1.24 g/cm ³																
Vapour pressure at 20°C	$<9.4 \times 10^{-7}$ Pa																
Henry's law constant at 25°C	$<9.2 \times 10^{-5}$ Pa m ³ /mol $<9.1 \times 10^{-10}$ atm m ³ /mol																
Ultraviolet (UV) – Visible spectrum	λ_{max} at 223 nm and 276 nm, with no other absorbance maxima between 350 and 750 nm																
Solubility in water at 25°C	4.2 mg/L																
Solubility in organic solvents at 25°C	<table> <tr> <th>Solvent</th><th>Solubility (g/L)</th></tr> <tr> <td>Acetone</td><td>300</td></tr> <tr> <td>Dichloromethane</td><td>400</td></tr> <tr> <td>Ethyl acetate</td><td>120</td></tr> <tr> <td>Methanol</td><td>66</td></tr> <tr> <td>n-hexane</td><td>42</td></tr> <tr> <td>Toluene</td><td>29</td></tr> <tr> <td>n-Octanol–water</td><td>4.8</td></tr> </table>	Solvent	Solubility (g/L)	Acetone	300	Dichloromethane	400	Ethyl acetate	120	Methanol	66	n-hexane	42	Toluene	29	n-Octanol–water	4.8
Solvent	Solubility (g/L)																
Acetone	300																
Dichloromethane	400																
Ethyl acetate	120																
Methanol	66																
n-hexane	42																
Toluene	29																
n-Octanol–water	4.8																
n-Octanol–water partition coefficient (K_{ow})	<table> <tr> <th>pH</th><th>log K_{ow}</th></tr> <tr> <td>7.5–7.7</td><td>3.2</td></tr> </table>	pH	log K_{ow}	7.5–7.7	3.2												
pH	log K_{ow}																
7.5–7.7	3.2																
Dissociation constant (pKa)	No dissociation between pH 1 and 12																
Stability (temperature, metal)	Stable to metals and elevated temperature																

End-Use Product—Revus Fungicide

Property	Result
Colour	Light beige
Odour	No particular odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	250 g/L nominal
Container material and description	High-density polyethylene (HDPE) (non-fluorinated and fluorinated), polyethylene terephthalate (PET) or co-extrusion (COEX) material, in sizes 250 mL to bulk
Density	1.07 g/mL
pH of 1% dispersion in water	6–8
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable in commercial packaging for one year at 20°C
Corrosion characteristics	Not corrosive to commercial packaging over one year at 20°C
Explosibility	Not explosive

1.3 Directions for Use

Revus Fungicide, when applied at 400–600 mL product/ha (100–150 g a.i./ha), is proposed to control, or suppress, specific diseases of greenhouse and field crops (refer to Table 1.3.1). The product can be applied as either an initial drench application or foliar spray for suppression of phytophthora blight on peppers, or as a foliar spray for all other diseases. Up to five applications of Revus Fungicide per season is proposed for most crops. Revus Fungicide is proposed to be tank mixed with Bravo 500 Agricultural Fungicide to increase the disease spectrum.

Table 1.3.1 Crop and Disease Claims Proposed for Revus Fungicide*

Crop and Crop Group	Diseases Controlled or Suppressed
Brassica Head and Stem subgroup: Broccoli, Chinese broccoli (gailon), Brussels sprouts, cabbage, Chinese cabbage (napa), Chinese mustard, cabbage (gai choy), cauliflower, cavalo broccoli, kohlrabi	Control of downy mildew (<i>Peronospora parasitica</i>)
Leafy Greens subgroup: Broccoli raab, cabbage, Chinese collards, kale, mizuna, mustard greens, mustard spinach, rape greens, including all cultivars and/or hybrids of these	

Crop and Crop Group	Diseases Controlled or Suppressed
Bulb Vegetables Dry bulb: Onion, bulb, garlic, shallot Green Onion: Green onions, leek, Welch onion	Control of downy mildew <i>(Peronospora destructor)</i>
Cucurbits: Cantaloupe, Chayote, Chinese-waxgourd, field cucumber, gourds, honeydew, melons <i>Momordica</i> spp. (bitter melon, balsam apple), muskmelon, watermelon, pumpkin, squash, zucchini, including cultivars and/or hybrids of these Greenhouse Cucumbers (For use in greenhouse only—not for transplant to the field)	Suppression of downy mildew <i>(Pseudoperonospora cubensis)</i> Suppression of phytophthora blight <i>(Phytophthora capsici)</i>
Fruiting Vegetables: Field peppers, bell peppers, non-Bell peppers, sweet non-Bell, eggplant, okra, ground cherry, pepino Greenhouse Peppers (For use in greenhouse only—not for transplant to the field)	Control of downy mildew <i>(Peronospora tabacina)</i> Suppression of phytophthora blight <i>(Phytophthora capsici)</i>
Field Tomato, Tomatillo Greenhouse Tomatoes (For use in greenhouse only—not for transplant to the field)	Control of late blight <i>(Phytophthora infestans)</i>
Grapes	Control of downy mildew <i>(Plasmopara viticola)</i>
Root and Tuber Vegetables Tuberous and Corm Vegetables subgroup: Arracacha, arrowroot, Chinese and Jerusalem artichoke, burdock, canna, edible bitter and sweet cassava, chayote (root), chufa, dasheen (Taro), ginger, leren, potato, sweet potato, tanier, turmeric, yam (bean), yam (true)	Control of late blight <i>(Phytophthora infestans)</i>
Leafy Vegetables: Field lettuce, leaf and head, spinach Greenhouse Lettuce (For use in greenhouse only—not for transplant to the field)	Control of downy mildew <i>(Bremia lactucae)</i> also known as blue mould <i>(Peronospora effusa)</i>

* It is recommended that Revus Fungicide be applied with a non-ionic adjuvant at 0.125% volume per volume dilution (v/v).

1.4 Mode of Action

Mandipropamid is classified as a Group 40 fungicide, and is part of the carboxylic acid amide (CAA) group of fungicides. The mode of action of CAA compounds has not yet been fully elucidated. Mandipropamid is a preventative fungicide with some curative activity, as it prevents spore germination and inhibits mycelial growth and sporulation. Mandipropamid binds to the waxy surface of plant tissues, and, once it is taken up, it is locally translocated to the opposite leaf surface.

2.0 Methods of Analysis

2.1 Methods Used to Analyse the Active Ingredient

The methods provided to analyse the active ingredient and the impurities in Mandipropamid Technical Fungicide have been validated and found to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided to analyse the active ingredient in the formulation has been validated and found to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

A residue analytical method (RAM) 415/01 (LC-MS/MS) was developed and proposed to determine levels of mandipropamid in crop matrices and for enforcement purposes. This method fulfilled the requirements as a data gathering method with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries were obtained in primary and secondary crop matrices. Adequate extraction efficiencies were demonstrated using radiolabelled lettuce samples analyzed using the RAM 415/01 enforcement method. Additionally, RAM 415/01 was validated by an independent laboratory. Conditions for analyte confirmation are not specified in RAM 415/01. As such, a confirmatory study or interference study for RAM 415/01 is required. Residue analytical method GRM 001.01.B (LC-MS/MS) was developed and proposed for the determination of the metabolite SYN 500003 in potato tubers and potato processed fractions. This method fulfilled the requirements as a data gathering method with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries were obtained in potato matrices. Mandipropamid was analyzed according to the American Food and Drug Administrations's (USFDA) Multiresidue Method Testing guidelines in Pesticide Analytical Methods (PAM) Volume I. The multiresidue testing data indicated that mandipropamid is not recovered through PAM, Volume I. Analytical methodologies are not required at this time for livestock matrices as finite residues of mandipropamid are not anticipated in ruminant matrices and there are no poultry feed items associated with the proposed uses.

High-performance liquid chromatography methods with ultraviolet detection or tandem mass spectrometry were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media. However, transformation products in sediment and water have not been addressed. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for mandipropamid was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and good laboratory practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to this chemical pest control product.

Mandipropamid was of low acute toxicity by the oral, dermal and inhalation routes of exposure in Wistar rats. It was minimally irritating to the skin and eyes of New Zealand White rabbits. Mandipropamid was negative for skin sensitization using the Guinea Pig Maximization and Local Lymph Node Assay methods.

Revus Fungicide was of low acute toxicity by the oral, dermal and inhalation routes of exposure in Wistar rats. It was minimally irritating to the skin and eyes of New Zealand White rabbit. Revus Fungicide was negative for skin sensitization using the Buehler method.

An extensive toxicokinetic assessment was carried out in the rat. In addition, a limited assessment was conducted in the dog. In the rat, there were dose-related differences observed in absorption, metabolism, distribution, and excretion and sex-related differences in excretion and absorption. Sex-related absorption and excretion differences were dose- and route-dependant in dogs.

In the rat, mandipropamid is rapidly but moderately absorbed following oral gavage dosing. Absorption was decreased at the high dose suggesting saturation of the absorption kinetics. Repeated dietary dosing did not demonstrate saturation. The maximum time (T_{max}) more than doubled in the high dose versus low dose with males about double that of females. Bile excretion accounted for a significant proportion of elimination with a wide range between sexes and dose levels. Urine was the least common route of excretion. Females excreted more radioactivity by urine due to the metabolite NOA 452422 glucuronide, which the males eliminated largely through bile and feces. Fecal excretion of radioactivity tended to be lower than bile excretion in males but not females. Elimination was virtually complete by 168 h.

The highest levels of residual radioactivity (<1%) occurred in the liver and kidney followed by pancreas, plasma and blood. More than half of the excreted product was mandipropamid glucuronide (mostly in urine for females and bile for males). Other major excretory products included parent compound in urine, feces and bile, metabolites SYN 534133 in urine and bile, CGA 380778 in the urine and feces and SYN 505503 glucuronide and SYN 505504 glucuronide in the urine. Although the excretion patterns for metabolites were different between the sexes, the plasma profiles were similar.

In the dog, absorption was 5–23% based on elimination in the urine. Absorbed mandipropamid was rapidly and extensively metabolized. There were no apparent differences in T_{max} in blood in the low or high dose groups after oral administration. After intravenous dosing, the T_{max} was 5.32 h in males and 3.17 h in females; these values decreased to 1 h in males and 3 h in females after the washout and single oral dose. In general, females took 1.7 to 2.5 times longer to reach maximum concentration (C_{max}) than males, although these differences were not observed in repeat high dose and intravenous dosed groups. The majority of the administered dose was eliminated in the feces, indicating a substantial contribution via biliary excretion for those dosed intravenously. The single high dose females excreted more radioactivity in the urine than the males and the other orally dosed groups. Urine was also a major route of elimination in the intravenous dosed animals.

Some accumulation/saturation occurred with repeat high dosing. Bioavailability of the oral dose was 44% for males and 78% for females. Doses of ≥ 100 mg/kg were poorly absorbed suggesting saturation. Repeated dosing did not appear to have an effect on the route or rate of metabolism in either sex, but increased the number of urinary metabolites. Major metabolites were parent compound in feces, and metabolites NOA 458422 glucuronide, CGA 380778 glucuronide, NOA 458422 sulfate and metabolite A (tentatively identified as O-glucuronide of NOA 446510) in urine. Minor metabolites included: CGA 380775 glucuronide in feces and urine, NOA 458422 in feces and urine, CGA 380778 in feces and urine and SYN 505503 in feces. Others were present at lower concentrations.

Short-term dermal studies showed mild erythema, edema and desquamation in the test groups after repeated application of mandipropamid to the shaved skin of rats. No systemic effects were observed.

In the short-term oral toxicity studies, the target organ was the liver with increases in liver weight, liver enzymes (dog), eosinophilia (mouse) and liver porphyrin pigmentation (dog). In contrast, in the long-term toxicity studies, the mouse did not display any adverse organ specific effects, while in the rat study the target organ was the kidney with effects such as roughened surface, chronic progressive nephropathy and renal osteodystrophia fibrosis. Decreases in body weight (mouse and rat) and in body-weight gain (mouse, rat and dog) were observed in both the short-term and long-term studies. In the long-term studies food consumption was also decreased.

There was no evidence of carcinogenic potential for mandipropamid in the mouse or the rat. The dose level chosen for the mouse study reached the maximum tolerated dose based on the decrease in body weight and in body-weight gain. Based on the body-weight gain data (decreased

body weight) and the lowest observed adverse effect levels (LOAEL) observed in the short-term studies using the rat, it was concluded that the maximum tolerated dose requirement was fulfilled. Mandipropamid was determined to be non-genotoxic in both the in vitro and in vivo mutagenicity studies.

There was no evidence of increased susceptibility of the young following in utero or early life exposure to mandipropamid. In the rat and rabbit developmental toxicity studies, there were no treatment-related effects on any maternal or fetal parameters up to the limit dose. In a two-generation reproductive toxicity study, pup weights were decreased in the F₁ and F_{2b} pups, thereby leading to an increase in time to preputial separation as a secondary effect. Adjusted liver weights were increased in F₁, F_{2a} and F_{2b} pups and the absolute liver weight was increased in the F_{2a} pups. In the parental animals, decreased body weight and body-weight gain was observed in the males at this dose level. In addition, increased absolute and adjusted kidney weights were observed in P males and females and F₁ females at this dose. There was no indication of reproductive toxicity.

No evidence of neurotoxicity was observed in either the acute or subchronic neurotoxicity studies in rats. No treatment-related clinical signs indicative of neurotoxicity were observed in short-term or long-term exposure studies in rats, mice, or dogs. Therefore, it was concluded that mandipropamid is not a neurotoxicant.

Several impurities identified in the technical grade active ingredient were also examined. For the impurities SYN 500003 and SYN 545038, one genotoxicity study per impurity was provided. The SYN 500003 was negative and the SYN 545038 was positive in the presence of metabolic activity in the Ames study. In addition, SYN500003 was tested for acute oral toxicity and demonstrated moderate toxicity. Both these impurities were present in the technical grade active mandipropamid test batch in sufficient quantities to ensure that the results of the mandipropamid studies covered the toxicity of the impurities.

Studies were also available for propargyl alcohol as, based on the molecular structure of mandipropamid, the potential exists for two propargyl alcohol molecules to be realized. However, it should be noted that in vivo metabolism studies conducted on mandipropamid did not result in the creation of propargyl alcohol. Propargyl alcohol and mandipropamid demonstrate similar liver effects in the rat and mouse. These effects include increased liver weights, induction of liver enzymes and histopathology.

Results of the acute and chronic tests conducted on laboratory animals with Mandipropamid Technical Fungicide and its associated end-use product, along with the toxicology endpoints for use in the human health risk assessment, are summarized in Appendix I, Tables 2, 3 and 4.

Pest Control Products Act Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to take into account the completeness of the data, as well as potential prenatal and postnatal toxicity

with respect to the exposure of and toxicity to infants and children. A different factor may be determined to be appropriate on the basis of reliable scientific data.

In considering the completeness of the toxicity database as it pertains to the exposure of and toxicity to infants and children, extensive data were available for mandipropamid with respect to the toxicity to infants and children, consisting of rabbit and rat developmental toxicity studies and a two-generation rat reproduction study. The prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to in utero exposure to mandipropamid. There was no indication of increased susceptibility in the offspring compared to parental animals in the reproduction study. On the basis of this information, the 10-fold factor required under the *Pest Control Products Act* was reduced to 1-fold.

3.2 Determination of Acute Reference Dose

An acute reference dose (ARfD) for mandipropamid was not required as there is no indication in the database that acute exposure will be of toxicological concern.

3.3 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) for mandipropamid is 0.05 mg/kg bw/day based on the no observed adverse effect level (NOAEL) of 5 mg/kg bw/day in the 12-month dog study (capsule). The NOAEL was based on minimal porphyrin staining in the liver and increased alkaline phosphatase and alanine transaminase activity at the 40 mg/kg bw/day LOAEL. This value represents the lowest NOAEL in the database. The standard uncertainty factor of 100 is required to account for interspecies extrapolation (10-fold) as well as intraspecies variability (10-fold). As described in the *Pest Control Products Act* Hazard Classification section, the 10-fold factor required under the *Pest Control Products Act* was reduced to 1-fold, resulting in a composite assessment factor (CAF) of 100-fold.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{5 \text{ mg/kg bw/day}}{100} = 0.05 \text{ mg/kg bw/day of mandipropamid}$$

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to Revus Fungicide is characterized as short- to intermediate-term for field uses and long-term for greenhouse uses and is predominantly by the dermal route.

Short-term and intermediate-term dermal

The no observed adverse effect level (NOAEL) of 1000 mg/kg bw/day from the 28-day dermal study in rats is considered the most appropriate endpoint for dermal exposure. This study was conducted at the limit dose and did not demonstrate any clinically adverse effects. The target

margin of exposure (MOE) of 100 includes a 10-fold uncertainty factor for interspecies extrapolation and a 10-fold uncertainty factor for intraspecies variability. No additional uncertainty factors were required. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Short-term and intermediate-term inhalation

The NOAEL of 41 mg/kg bw/day from the 90-day dietary study in rats is considered the most appropriate study, given no studies of appropriate duration conducted via the inhalation route were available. This NOAEL is based on decreases in body weight, body-weight gain and food consumption at the LOAEL of 260 mg/kg bw/day. The target MOE of 100 includes a 10-fold uncertainty factor for interspecies extrapolation and a 10-fold uncertainty factor for intraspecies variability. No additional uncertainty factors were required. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Long-term dermal

The NOAEL of 1000 mg/kg bw/day from the 28-day dermal study in rats is considered the most appropriate endpoint for dermal exposure. This study was conducted at the limit dose and did not demonstrate any clinically adverse effects. The target MOE of 300 includes a 10-fold uncertainty factor for interspecies extrapolation and a 10-fold uncertainty factor for intraspecies variability. In addition, a threefold uncertainty factor was applied for durational extrapolation from a short-term study. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Long-term inhalation

The NOAEL of 5 mg/kg bw/day from the one-year dietary study in dogs is considered the most appropriate study, given no studies of appropriate duration conducted via the inhalation route were available. This NOAEL is based on porphyrin pigmentation in the liver and increased liver enzymes at the LOAEL of 40 mg/kg bw/day. The target MOE of 100 includes a 10-fold uncertainty factor for interspecies extrapolation and a 10-fold uncertainty factor for intraspecies variability. No additional uncertainty factors were required. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

3.4.1.2 Dermal Absorption

Since a dermal NOAEL was used in the risk assessment, a dermal absorption value was not required.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for exposure to Revus Fungicide during mixing, loading and application. Dermal and inhalation exposure estimates for workers mixing/loading and applying Revus Fungicide to field and greenhouse crops were generated from the Pesticide Handlers Exposure Database (PHED).

Exposure to workers mixing, loading and applying Revus Fungicide is expected to be short- to intermediate-term in duration for field crops and long-term for greenhouse crops and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying Revus Fungicide to the Brassica, Bulb Vegetable, Cucurbit, Fruiting Vegetable, Root and Tuber Vegetable and Leafy Vegetable crop groups plus field tomatoes and grapes using ground or aerial application equipment and to greenhouse vegetables using handheld spray equipment. The exposure estimates are based on mixers/loaders/applicators wearing long-sleeved shirts, long pants, shoes plus socks, and chemical-resistant gloves during mixing/loading.

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (no observed adverse effects levels) to obtain the MOE; the target MOE is 100 for short-term to intermediate-term exposure for both inhalation and dermal exposure. For long-term exposure, the target MOE is 100 for inhalation exposure and 300 for dermal exposure.

Table 1 Mixer/Loader/Applicator Dermal and Inhalation Exposure Estimates and MOEs

Crop Group	Application Method	Area Treated per Day (ha)	Dermal Exposure ^a mg/kg bw/day	Dermal MOE ^b	Inhalation Exposure ^a mg/kg bw/day	Inhalation MOE ^c
Brassica, Bulb Vegetables, Cucurbits, Fruiting Vegetables, Leafy Vegetables, Field tomatoes	Groundboom – Farmer	32	0.0058	173 000	0.00018	234 000
	Groundboom – Custom Applicator	80	0.014	69 300	0.00044	93 400
	Aerial Mix/Load	490	0.054	18 600	0.0017	24 400
	Aerial Applicator	490	0.010	98 600	0.00007	558 000
Grapes	Airblast	16	0.030	33 200	0.00025	162 000
Root and Tuber Vegetables	Groundboom – Farmer	80	0.014	69 300	0.00044	93 400
	Groundboom – Custom Applicator	300	0.054	18 500	0.0017	24 900
	Aerial Mix/Load	490	0.054	18 600	0.0017	24 400
	Aerial Applicator	490	0.010	98 600	0.00007	558 000
Greenhouse Vegetables	Low Pressure Handwand	1	0.0020	495 000	0.00010	423 000
	High Pressure Handwand	1	0.012	83 600	0.00032	15 500
	Backpack	1	0.012	85 700	0.00013	37 600

^a Exposure Estimates = PHED Exposure (µg ai/kg ai handled) × Rate × Area Treated per Day (ha/day)
 \times Dermal Absorption Factor
 bw (70kg)

^b Dermal MOE = $\frac{\text{NOAEL (1000 mg/kg bw/d)}}{\text{exposure estimates (mg/kg/day)}}$ For short-term to intermediate-term exposure the target MOE is 100; for greenhouse (long-term) scenarios, the target MOE is 300.

^c Inhalation MOE = $\frac{\text{NOAEL (mg/kg bw/d)}}{\text{exposure estimates (mg/kg/day)}}$ For short-term to intermediate-term exposure, a NOAEL of 41 mg/kg bw/day with a target MOE of 100 was used. For greenhouse (long-term) scenarios, a NOAEL of 5 mg/kg bw/day with a target MOE of 100 was used.

As the MOEs are above the target, exposure for workers mixing/loading and applying Revus Fungicide to Brassica, Bulb Vegetable, Cucurbit, Fruiting Vegetable, Root and Tuber Vegetable and Leafy Vegetable crop groups, grapes and greenhouse vegetables is considered acceptable with the personal protective equipment of long-sleeved shirts, long pants, shoes plus socks and chemical-resistant gloves during mixing/loading and long-sleeved shirts and long pants during application.

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with Revus Fungicide to perform routine re-entry activities, such as scouting, weeding, harvesting and thinning. Inhalation exposure is expected to be minimal. The duration of exposure is considered to be intermediate-term for field crops and long-term for greenhouse vegetables, and the primary route of exposure for workers re-entering treated areas would be through dermal contact with treated foliage.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. A tier one risk assessment was done based on a crop grouping approach. As such, the highest transfer coefficient application rate and number of applications (five) for each crop group were used to estimate exposure for each crop group. Chemical-specific dislodgeable foliar residue data were not submitted. Therefore, a default dislodgeable foliar residue value of 20% of the application rate and a dissipation rate of 10% per day were used in the exposure assessment for field vegetables. For greenhouse vegetables, a default dislodgeable foliar residue value of 20% of the application rate was also used, but no dissipation was assumed.

Exposure estimates were compared to the toxicological endpoint to obtain the MOE; the target MOE is 100 for intermediate-term and 300 for long-term exposures.

Table 2 Postapplication Margin of Exposure on Field Crops and Greenhouse Vegetables

Activity	Transfer Coefficient (cm ² /hr)	Exposure (mg/kg bw/day) ^a	Margin of Exposure ^b
Hand harvesting, hand pruning and topping in Brassica	5000	0.256	3910
Hand harvesting and thinning in Bulb Vegetables	2500	0.160	6250
Hand harvesting, leaf pulling, hand pruning, thinning and turning in Cucurbits	2500	0.160	3250
Hand harvesting, staking, tying and hand pruning in Fruiting Vegetables and Field tomatoes	1000	0.064	15 600

Activity	Transfer Coefficient (cm ² /hr)	Exposure (mg/kg bw/day) ^a	Margin of Exposure ^b
Cane turning and girdling in Grapes	19300	1.235	810
Hand harvesting in Root and Tuber Vegetables	2500	0.160	6250
Hand harvesting and thinning in Leafy Vegetables	2500	0.160	6250
All activities in Greenhouse Vegetables	1800	0.309	3241

^a Estimated as 20% application rate × transfer coefficient (cm²/hour) × 8 hour/day worked × 100% dermal absorption / 70 kg body weight.

^b NOAEL (1000 mg/kg bw/day)/Exposure; target MOE is 100 for intermediate-term and 300 for long-term exposures.

Given the MOEs are above the target, exposure to workers entering fields and greenhouses treated with Revus Fungicide is considered acceptable on the day of the fifth application, i.e. the day expected to have the highest potential exposure.

3.4.3 Residential Exposure and Risk Assessment

Given there are no residential uses, no residential exposure is expected.

3.4.4.3 Bystander Exposure and Risk

Bystander exposure should be negligible, given the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity, such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for enforcement purposes is mandipropamid in primary crops, rotational crops and animal commodities. For risk assessment purposes, the residue definition is mandipropamid in primary crops, except root and tuber vegetables, and in rotational crops and animal commodities; and is mandipropamid and the metabolite SYN 500003 in root and tuber vegetables. The data gathering/enforcement analytical methodology RAM 415/01 liquid chromatography with tandem mass spectrometry (LC/MS/MS) is valid for the quantification of mandipropamid residues in crop commodities. The data gathering method GRM 001.01.B (LC/MS/MS) is valid for the quantification of SYN 500003 in potato tubers and processed potato commodities. The residues of mandipropamid are stable when stored in a freezer at -20°C for 24 months. Raw agricultural commodities were processed, and mandipropamid residues were found to concentrate in potato wet peel, raisins and tomato paste. Supervised residue trials conducted

throughout the United States and greenhouse trials in Europe using end-use products containing mandipropamid at 0.75–1.2× the approved label rates in or on cabbage, broccoli, mustard greens, cucumber, cantaloupe, summer squash, dry bulb onion, green onion, bell peppers, non-Bell peppers, tomatoes, grapes, leaf lettuce and head lettuce, celery, spinach, potato, greenhouse cucumbers and greenhouse tomatoes and at 0.49–0.52× the approved label rates in or on greenhouse lettuce are sufficient to support the proposed maximum residue limits.

3.5.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model–Food Commodity Intake Database (DEEM–FCIDTM Version 2.03), which uses updated food consumption data from the United States Department of Agriculture’s Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following assumptions were made in a refined chronic analysis: default and experimental processing factors, median values for certain commodities and American tolerances for all other commodities. The refined chronic dietary exposure from all supported mandipropamid food uses (alone) for the total population and all representative population subgroups is ≤5.0% of the ADI. The PMRA estimates that chronic dietary exposure to mandipropamid from food and water is 3.6% (0.001822 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1 to 2 yrs at 5.3% (0.002669 mg/kg bw/day) of the ADI. Aggregate exposure from food and water is considered acceptable.

3.5.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for mandipropamid consists of exposure from food and drinking water sources only; there are no residential uses. Aggregate risks were calculated based on chronic endpoints. No acute endpoint was identified for the general population, including infants and children.

3.5.4 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Leafy <i>Brassica</i> greens (Crop Subgroup 5B)	25.0
Leafy vegetables, except <i>Brassica</i> (Crop Group 4)	20.0
Green onion subgroup (Crop Subgroup 3-07B)	4.0
Head and stem <i>Brassica</i> (Crop Subgroup 5A), raisins	3.0
Grapes	1.4
Fruiting vegetables (Crop Group 8), okra	1.0
Cucurbit vegetables (Crop Group 9)	0.6
Bulb onion subgroup (Crop Subgroup 3-07A)	0.05
Tuberous and corm vegetables (Crop Subgroup 1C)	0.01

For additional information on Maximum Residue Limits (MRLs) in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodology, field trial data, greenhouse trial data and the chronic dietary risk estimates are summarized in Appendix I, Tables 1, 5 and 6.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Mandipropamid enters the terrestrial environment when it is used as a fungicide on a variety of crops, including fruits and vegetables. The main dissipation route of mandipropamid in the terrestrial environment is biotransformation. Mandipropamid is slightly to moderately persistent in soil and dissipates with half-lives of 14–86 days under laboratory conditions and 27.5–102.8 days under field conditions. No major transformation products were detected in soil. A large portion of the applied radioactivity was determined to be non-extractable residue in laboratory soil biotransformation studies (30.9 to 45.5% applied radioactivity under aerobic conditions and 34.6 to 37.1% under anaerobic conditions). This non-extractable residue was determined to be associated with humic substances. Phototransformation will contribute to the dissipation of mandipropamid in the terrestrial environment, although this process will not contribute significantly as the half-life determined at 40°N ranged between 32.5 and 46.4 days. Henry's law constant ($<9.1 \times 10^{-10}$ atm m³/mol) indicates that mandipropamid is not expected to

volatilize from moist soil surfaces. Adsorption data indicates that mandipropamid has low mobility in soil ($K_{\text{oc}} = 411\text{--}1228$). Following desorption, a large portion (31.8 to 53.7%) of the applied radioactivity remained adsorbed to the soil, indicating that the non-extractable residues determined in the biotransformation study may not be bioavailable. The leaching assessment using groundwater ubiquity score (GUS)⁴ indicates that mandipropamid is a borderline leacher under certain conditions. In addition, only a few of the Cohen⁵ criteria are met for mandipropamid. Mandipropamid may leach in certain types of soils, although the active ingredient was not observed below 15 cm in the field dissipation studies. Groundwater modeling, which used a scenario that would result in the largest amount of leaching, indicated that low levels of mandipropamid may be detected in groundwater. As a result, the PMRA does not consider mandipropamid to be a significant concern regarding leaching.

The available data on the persistence of the transformation products of mandipropamid indicate that they are non-persistent in soil. No major transformation products were detected in laboratory soil studies (see Appendix I, Table 7); thus, these transformation products will not be available for leaching nor runoff from the application site.

Mandipropamid has low solubility in water (4.2 mg a.i./L) and can enter the aquatic environment through spray drift and runoff from the application site. In the aquatic environment, mandipropamid dissipates rapidly from the water layer via partitioning. Phototransformation will also contribute to the dissipation of mandipropamid from the water layer in the photic zone. Mandipropamid is stable to hydrolysis and is not expected to volatilize; therefore, these two processes will not affect the dissipation of mandipropamid from the aquatic environment.

Biotic transformation will affect the dissipation of mandipropamid in the aquatic environment; thus, it results in a classification of non-persistent to slightly persistent in the total system ($\text{DT}_{50} = 7.8\text{--}25.8$ d). As a result of the rapid partitioning of mandipropamid from the water layer, the dissipation of mandipropamid in aquatic systems is driven by biotransformation in the sediment. During the aquatic biotransformation studies, it was determined that a large portion of the AR became incorporated into non-extractable residues (36.5 to 48.1% under aerobic conditions, 16.2 to 30.9% under anaerobic conditions). These non-extractable residues were determined to be associated with humic substances in the sediment. Under more realistic environmental conditions (outdoor pond), mandipropamid dissipated with a total system DT_{50} of 5.4 days.

The transformation products SYN539678, SYN504851 and SYN521195 were identified as major in at least one aquatic laboratory study. Individual fate studies were not submitted to determine the persistence of the transformation products in aquatic systems. The Organisation for Economic

⁴ Gustafson, D.I. (1989) Groundwater Ubiquity Score: A Simple Method for Assessing Pesticide Leachability. *Environ. Toxicol. Chem.* 8: 339–357.

⁵ Cohen, S.Z., S.M. Creeger, R.F. Carsella and C.G. Enfield (1984) Potential for Pesticide Contamination of Groundwater Resulting from Agricultural Uses. *In* R.F. Druggier and J.N. Seiber, eds., *Treatment and disposal of Pesticide Wastes*. ACS symposium Series No. 259. American Chemical Society, Washington, DC, pp.297–325.

Co-operation and Development (OECD-RMS) calculated DT₅₀s for the transformation products identified in the aerobic and anaerobic water/sediment studies using a multi-compartmental model that takes into consideration the formation and decline of the product in addition to the interaction between the water and sediment. Based on these DT₅₀s, the transformation products ranged from non-persistent to moderately persistent under aerobic and anaerobic conditions. The DT₅₀ for SYN504851 could not be determined given that no decline had occurred at study termination.

The structure and percent detected of the major and minor transformation products of mandipropamid are presented in Appendix I, Table 7. Data on the fate and behaviour of mandipropamid and its transformation products are summarized in Appendix I, Tables 8 and 9.

4.2 Effects on Non-Target Species

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models that take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats, including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity, as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening-level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ($RQ = \text{exposure/toxicity}$), and the risk quotient is then compared to the level of concern ($LOC = 1$). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Effects on Terrestrial Organisms

Risks of mandipropamid, its related end-use product and transformation products to terrestrial organisms were based upon the evaluation of toxicity data for the following (see Appendix I, Table 10):

- one earthworm species, one bee species and two other arthropods representing invertebrates (acute and long-term exposure);
- two bird and two mammal species representing vertebrates (acute gavage, short-term and long-term, reproduction, dietary exposure); and,
- ten crop species representing non-target vascular plants.

Terrestrial Invertebrates

Two earthworm toxicity studies for mandipropamid and one of its transformation products (CGA380778) were submitted. Mortality was not observed in either study at the highest rate tested (1000 mg/kg soil), although a significant decrease in body weight was observed in both studies with a no observed effect concentration (NOEC) of 100 mg/kg soil. Risk quotients calculated for the screening level did not exceed the level of concern (see Appendix I, Table 12). The use of mandipropamid is not expected to pose a risk to earthworms.

Mandipropamid is relatively non-toxic to honeybees according to the classification of Atkins et al. (1981)⁶ with acute contact and acute oral LD₅₀s being >200 µg a.i./bee and >160 µg a.i./bee, respectively. Both LD₅₀s represent the highest dose tested with no sub-acute effects noted at any concentration tested. According to Atkins et al. (1981), the LD₅₀ in micrograms per bee (µg/bee) can be converted to the equivalent application rate in kg a.i./ha by multiplying µg/bee by 1.12. After conversion, the acute oral LD₅₀ value is >224 g a.i./ha and the acute contact LD₅₀ value is >179.2 g a.i./ha. An RQ was calculated using the following equation: LD₅₀/EEC; where the EEC is the proposed maximum single application rate of 150 g a.i./ha. The RQs calculated and presented in Appendix I, Table 12 do not exceed the level of concern. The use of mandipropamid is not expected to pose an acute risk on a contact or oral basis. Toxicity studies for beneficial arthropods were not submitted to the PMRA. However, these studies were submitted to and reviewed by the OECD-RMS. The results were summarized in the OECD monograph and considered in this assessment.

The studies reviewed by the OECD-RMS indicated that mandipropamid is non-toxic for most predator and parasite species, although toxicity was noted with the parasitic wasp and the LR₅₀ of 827 g a.i./ha was used to calculate a risk quotient. The maximum seasonal rate that was considered for this assessment was 600 g a.i./ha (4 applications × 150 g a.i./ha) without considering any dissipation between applications. This maximum seasonal rate was used as the EEC in determining the RQ, which did not exceed the level of concern (see Appendix I, Table 12). The use of mandipropamid is not expected to pose a risk to beneficial arthropods.

⁶ Atkins, E.L., Kellum, D., Atkins K.W. 1981. *Reducing pesticide hazards to honeybees: mortality prediction techniques and integrated management techniques*. University of California, Division of Agricultural Sciences, Leaflet 2883. 22 pp.

Terrestrial Plants

Seedling emergence and vegetative vigour studies on ten crop species were submitted to the PMRA for review. No adverse effects on seedling emergence were noted at application rates up to 750 g a.i./ha. Similarly, no adverse effects on vegetative vigour were noted for the ten crop species at the highest dose tested, 900 g a.i./ha. The EC₂₅ for seedling emergence and vegetative vigour were set at >750 g a.i./ha and >900 g a.i./ha, respectively. The maximum seasonal application rate was 600 g a.i./ha, not taking into consideration the dissipation between applications that was considered for this assessment. The RQ determined indicates that the level of concern was not exceeded for terrestrial plants (Appendix I, Table 12). The use of mandipropamid is not expected to pose a risk to terrestrial plants.

Terrestrial Vertebrates

Acute and reproductive toxicity studies using mallard duck and bobwhite quail were submitted to the PMRA. The acute toxicity studies (oral and dietary) indicated that mandipropamid is practically non-toxic to birds with no mortality occurring at the highest dose tested in both study types. No avian reproductive effects were noted at the highest dose tested in the reproduction studies. Similarly, the acute oral and dietary studies for small mammals indicate that mandipropamid is practically non-toxic to small mammals with no mortality occurring at the highest dose tested in both study types. However, the small mammal dietary study demonstrated a significant decrease in body-weight gain at doses of 260 mg a.i./kg bw. The two-generation study demonstrated effects on pup body weights at dietary concentrations of greater than 250 mg a.i./kg diet (22.9 mg a.i./kg bw).

Because exposure is dependent on the body weight of the organisms and the amount and type of food consumed, the screening level risk assessment for birds and mammals considers a set of generic body weights (20, 100, 1000 g for birds and 15, 35, 1000 g for mammals) and food preferences (100% small insects for insectivores, 100% fruits for frugivores, 100% grain and seeds for granivores and 100% leaves and leafy crop for herbivores; food items considered at the screening level provide the most conservative EEC for each food guild). To account for dissipation of food sources, a default half-life of 35 days was used at the screening level. This default was based on a data set of 447 foliar half-lives acquired from an extensive literature review⁷. The 35 day half-life is the maximum half-life for insecticides and the second largest value in the entire dataset. Additionally, the acute toxicity endpoint is divided by a factor of 10 to account for potential differences in species sensitivity, as well as varying protection levels (e.g. community, population, individual).

The calculated screening level risk quotients for birds and mammals (Appendix I, Table 13) indicate that the level of concern was not exceeded except for two instances. For 1 kg and 0.035 kg mammals, the herbivore level of concern was exceeded for reproductive effects and, as a result, a refined assessment was conducted.

⁷ Willis, G.H., and McDowell, L.L. 1987. Pesticide persistence on foliage. *Reviews of Environmental Contamination and Toxicology*. 100:23-73.

Given the conservative assumptions taken in the screening level assessment, a refined assessment was conducted to further characterize the reproductive risk to herbivore mammals (Appendix I, Table 15). Instead of using the highly conservative plant half-life of 35 days, a half-life of 10 days was used. This half-life was obtained from the same data set (Willis and McDowell, 1987) and is still considered conservative given that 93% of the foliar half-lives within this data set are less than 10 days. An on-field assessment was conducted taking into consideration additional types of vegetation for the diet of herbivores. In addition, the risk associated with the consumption of food items contaminated from spray drift off the treated field was also assessed taking into consideration the spray drift deposition for medium sized spray droplets for both ground (11%) and aerial spray (23%). The reproduction level of concern was exceeded for small mammals of approximately 35 g feeding on short grass on the treated field; however, when the RQ was calculated for the off-field assessment, the level of concern was not exceeded. The on-field assessment assumes that the animal is feeding exclusively on treated food immediately after the final application of mandipropamid. Given the conservative nature of this assessment along with the fact that the LOC was only slightly exceeded, the PMRA concludes that reproductive risk to small mammals is expected to be negligible.

4.2.2 Effects on Aquatic Organisms

Risk of mandipropamid, its related end-use product and transformation products to freshwater aquatic organisms was based upon the evaluation of toxicity data for the following (Appendix I, Table 14):

- one invertebrate species: daphnid (acute and long-term exposure);
- two fish species (acute and long-term exposure);
- one green algae, one blue-green algae, and one vascular plant; and,
- amphibian species using fish as surrogate.

Risk of mandipropamid to marine aquatic organisms was based upon evaluation of toxicity data for the following (Appendix I, Table 14):

- two invertebrates: mysid and eastern oyster (acute exposure), and
- one fish species (acute exposure).

Aquatic organisms can be exposed to mandipropamid as a result of drift and runoff. To assess the potential for effects from exposure to mandipropamid and its transformation products, the screening level EECs in the aquatic environment, based on direct application to water, were used as exposure estimates. The calculated EECs were those determined in 15 cm of water for amphibians and 80 cm of water for all other aquatic organisms. For the screening level risk assessment for aquatic organisms, the laboratory endpoints were adjusted using factors to account for differences in species sensitivity and protection goals (e.g. community, population and individual).

Aquatic Invertebrates—Freshwater and Marine

The acute toxicity studies with mandipropamid using *Daphnia magna* demonstrated mortality/immobility with a 48-h EC_{50} of 7.1 mg a.i./L, whereas the acute toxicity study using the transformation product CGA380778 resulted in a 48-h EC_{50} of 55.9 mg TP/L. Similar acute toxicity for mandipropamid to marine invertebrates was demonstrated in a 96-h LC_{50} of 1.7 mg a.i./L. Shell deposition for marine mollusk was affected at an EC_{50} of 0.97 mg a.i./L. Reproductive effects of *Daphnia magna* were noted for mandipropamid at a NOEC of 0.87 mg a.i./L for the number of live offspring. Calculated risk quotients for both freshwater and marine invertebrates demonstrate that the level of concern for acute and reproductive effects was not exceeded; therefore, the PMRA does not expect adverse effects on aquatic invertebrate populations as a result of the application of mandipropamid (Appendix I, Table 14).

Fish—Freshwater and Marine

Acute toxicity studies with mandipropamid were submitted for two freshwater fish and one marine fish species. The endpoints for mortality were similar for the freshwater fish (rainbow trout, 96-h LC_{50} = 4.4 mg a.i./L) and marine fish (sheepshead minnow, 96-h LC_{50} = 4.5 mg a.i./L). Reproductive effects were noted on fry survival at a NOEC of 0.48 mg a.i./L. Calculated risk quotients for both freshwater and marine fish demonstrate that the level of concern for acute and reproductive effects was not exceeded; therefore, the PMRA does not expect adverse effects on fish populations as a result of the application of mandipropamid (see Appendix I, Table 14).

Aquatic Plants

Acute studies for freshwater algae and vascular plants were submitted to the PMRA for exposure to mandipropamid and CGA380778. The endpoints determined for acute exposure were $EC_{50} > 2.5$ mg a.i./L and $EC_{50} > 4.3$ mg a.i./L for mandipropamid to algae and vascular plants, respectively. The PMRA considered the endpoints of additional transformation toxicity studies that were reviewed by the OECD-RMS. The calculated risk quotients indicate that the level of concern for acute exposure to aquatic plants does not exceed the level of concern; therefore, the PMRA does not expect adverse effects on aquatic plants as a result of the application of mandipropamid (see Appendix I, Table 14).

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

5.1.1.1 Control of Downy Mildew (*Peronospora parasitica*) on Brassicas: Including the Head and Stem Subgroup, and the Leafy Greens Subgroup

Eight American trials were submitted for review. Tested rates ranged from 100–150 g a.i./ha, applied at 7–14 day intervals, with between 3 and 7 consecutive applications per year. Chinese broccoli (var. Kailaan, and an unspecified variety) was tested in seven of the trials, and one trial assessed an unspecified variety of broccoli. Trials also assessed Revus Fungicide applied alone and with various adjuvants (non-ionic surfactant, organosilicone surfactant).

Results were consistent across all trials, demonstrating that Revus Fungicide applied at 100–150 g a.i./ha resulted in good disease control compared to the check treatments. A general trend was noted with respect to the rate and application interval, with the higher rate of 150 g a.i./ha and shorter application intervals (seven to ten days) providing the greatest disease control. Statistically greater disease control at the 150 g a.i./ha rate compared to the 100 g a.i./ha rate was only noted under conditions of high disease pressures; however, given not all trials directly compared Revus Fungicide at different rates, this trend could not be confirmed. When compared to the commercial standard, Revus Fungicide at 100 and 150 g a.i./ha performed as well or better with respect to disease incidence and/or disease severity control. Application of Revus Fungicide and an adjuvant showed that there was an increase in the efficacy of Revus Fungicide when applied with non-ionic adjuvant at 0.125% volume per volume dilution (v/v). Application of Revus Fungicide with X77, an organosilicone surfactant, resulted in significant phytotoxicity in one trial. This result was not seen in other trials where the same surfactant was tested.

Crop Grouping

Two Brassica crops were tested: Chinese broccoli (with only one variety of Chinese broccoli clearly identified) and broccoli. Based on the limited number of crops tested, only the Head and Stem sub-group can be fully supported (broccoli, Chinese broccoli, Brussels sprouts, cabbage, Chinese cabbage, Chinese mustard cabbage, cauliflower, cavalo broccoli and kohlrabi). However, the Brassica leafy greens crop subgroup can be conditionally supported.

5.1.1.2 Control of Downy Mildew (*Peronospora destructor*) on Bulb Vegetables: Dry Bulb (Onion, Garlic, Shallot) and Green Onion (Green Onions, Leeks, Welsh Onion).

Three trials conducted in the United States (Michigan, New York, Oregon) on dry bulb onions were submitted for review. Revus Fungicide was applied between four and six times, at rates of 100 or 150 g a.i./ha, and was applied alone, with a non-ionic surfactant, or with a mineral oil/surfactant at 0.0625–1.0% v/v. All applications were made on seven day intervals, but the proposed 10-day application interval was not tested. No statistical analysis was provided for any of the onion data. Revus Fungicide was not tested with a silicone-based adjuvant, as proposed.

In general, under low to moderate disease pressures, Revus Fungicide applied alone was effective in controlling downy mildew disease severity or incidence at the 100 g a.i./ha rate. In two of the trials, no differences in disease control or defoliation were observed between the two rates (100 vs. 150 g a.i./ha) when applied alone. In the one trial where there was a difference, a single disease assessment was made after six consecutive applications, which is outside of the proposed use pattern. The efficacy of the product at 100 and 150 g a.i./ha was greatly increased when applied with a non-ionic surfactant at 0.125% v/v or with a crop oil concentrate (1% v/v). There was no difference in the level of disease control between the 100 or 150 g a.i./ha treatments when both rates were applied with a surfactant or crop oil. No phytotoxicity was reported in the three trials. Further trials testing the product as proposed for use would be recommended to confirm whether the 150 g a.i./ha rate is required, to test the application with a silicone-based adjuvant, and to determine whether the 10-day application interval is appropriate.

Crop Grouping

Two trials were conducted on dry bulb onions, and the third onion variety was not specified. Based on this lack of evidence, there is insufficient data to fully support a full crop grouping claim for all bulb vegetables, and only dry bulb onions can be fully supported. However, based on the similarity of bulb vegetables, this claim can be conditionally supported on garlic, shallot, green onions, leek and Welch onion.

5.1.1.3 Suppression of Downy Mildew (*Pseudoperonospora cubensis*) on Field Cucurbits, and Greenhouse Cucumbers

A total of ten field trials conducted on cantaloupe (five studies), cucumber (two studies) and pumpkin (three studies) were submitted. Trials were conducted in the United States (Texas, Florida, Alabama and Illinois) between 2002 and 2006. Revus Fungicide was tested at rates between 100 and 250 g a.i./ha, applied alone, with an adjuvant, or in alternation with other fungicides. Between 2 and 10 applications per season were made, at intervals of 2–14 days. Statistics were presented in only two of the ten trials.

For efficacy, two of the trials were not assessed due to very low disease pressures, and two trials were not assessed as various unforeseen circumstances heavily influenced the study, thus confounding the results (tropical storms and hurricanes resulted in torrential rainstorms and potentially washed away the fungicide when applied). Another trial was also not assessed, as 10 consecutive applications were made before assessing for disease, which is well above the requested use pattern.

Based on the lack of statistics conducted on the trial data, trends in the results can only be described. There was consistency across the trials and crops demonstrating that, under moderate and high disease pressures, Revus Fungicide applied alone at 100–150 g a.i./ha with a 7–10 day application interval provided acceptable control of downy mildew compared to the untreated check. Results also suggested a marked increase in efficacy when Revus Fungicide is applied with an adjuvant. When applied with a non-ionic adjuvant (0.125 % v/v) Revus Fungicide at 100 g a.i./ha resulted in similar efficacy to the 150 g a.i./ha rate without the adjuvant. Under high disease pressures, Revus Fungicide applied at 150 g a.i./ha provided slightly better disease

control than at the 100 g a.i./ha. Since there were no trials that directly compared Revus Fungicide to a commercial standard, a direct comparison cannot be made. There was sufficient evidence to support the proposed crop group, and the proposed application interval of seven to 10 days.

Based on a request from the registrant, the level of disease management for Revus Fungicide on cucurbit downy mildew will be suppression and not control. In addition, based on information regarding the use of Revus Fungicide on greenhouse cucumbers, a precautionary phytotoxicity statement will be added to the label.

5.1.1.4 Suppression of Phytophthora Blight on Field Cucurbits and Greenhouse Cucumbers

Two 2006 American field studies were conducted in Illinois (pumpkin) and Georgia (edible gourd) to support this claim. For each trial, Revus Fungicide was not tested alone, but as part of an alternation program with other fungicides or in a tank mix with other fungicides. Therefore, it is not possible to assess Revus Fungicide for this claim. Based on insufficient evidence testing Revus Fungicide applied alone and according to the proposed use pattern, this claim cannot be supported.

5.1.1.5 Control of Downy Mildew (*Peronospora tabacina*) on Fruiting Vegetables (Field) and Greenhouse Peppers

No data on this pathogen were submitted in support of this claim; therefore, it cannot be supported.

5.1.1.6 Suppression of Phytophthora Blight (*Phytophthora capsici*) on Fruiting Vegetables (Field) and Greenhouse Peppers

Fourteen trials were submitted in support of this claim; however, nine of them could not be assessed for various reasons, including the following:

- disease pressures were too low;
- Revus Fungicide was not tested as per the proposed directions for use, or was applied alone (only in rotation or else in a tank mix with other fungicides);
- Revus Fungicide was not applied as per the proposed application method (foliar vs. drench);
- assessments were made only at the end of the season;
- above-label consecutive applications (eight or more) were made before the first assessment was made;
- the trials were conducted such that application rates could not be determined or confirmed in the study; and
- the assessment made on chili pepper plants may not be applicable to Bell peppers (a rate adjustment may be required to reflect the greater surface area of Bell peppers).

Of the remaining five trials, all studies applied the product as a soil drench for the initial application and then reapplied it either as a drench or as a foliar spray.

Of the five trials that were assessed, Revus Fungicide was tested at 150 or 300 g a.i./ha, and applied at 7-, 10- or 14-day intervals. For all trials, a drench application was used as the first application. The disease was directly assessed by measuring the percentage of dead plants, percentage wilted plants, percentage of disease incidence, and the area under the disease progress curve (AUDPC).

Results across the trials indicate that when Revus Fungicide was applied as a soil drench immediately after planting, followed by foliar spray applications, there was a significant decrease in the percent plants with symptoms, the percent disease severity, the percent mortality and the AUDPC, and a significant increase in the duration of plant survival (days) compared to the untreated control. No differences were noted in the marketable or non-marketable yield. Notable differences in the level of disease control varied based on the application interval (applications made closer together having greater results), the number of sequential applications and the level of disease pressures reported in the studies. No phytotoxicity was reported in any of the trials. One study reported that increasing the application rate to 300 g a.i./ha resulted in an increased mortality rate (60% for the 300 g a.i./ha rate, compared to 30% for the 150 g a.i./ha rate).

No trials were submitted that tested the product according to the proposed claims of suppression of this disease. In addition, because there are no alternatives currently registered in Canada for this use, and resistance management practices must be adhered to, a maximum of one seasonal application may be made immediately before transplanting out.

There was sufficient evidence to conditionally support this claim, based on applying Revus Fungicide as a drench application immediately before transplanting in the field. Based on residue concerns, it is not to be used for greenhouse-grown peppers. Extensive confirmatory efficacy data are requested.

5.1.1.7 Control of Downy Mildew (*Plasmopara viticola*) on Grapes

Two trials conducted in the United States (New York) in 2002 were submitted for review. Revus Fungicide was tested alone at 125 g a.i./ha, applied between 4 and 7 times per season at 7-day intervals. Revus Fungicide was not applied with any adjuvant or additive. No statistical analysis was conducted on the data.

Results demonstrated that under low disease pressures, Revus Fungicide applied at 125 g a.i./ha resulted in moderate disease control of downy mildew on grape leaves (40% disease severity control). Under moderate to high disease pressures, it resulted in good to excellent control of disease severity on immature fruit (100% disease severity control), and mature fruit (94–99% control in two trials). No phytotoxicity was reported in any of the trials, including after 7 consecutive applications at 125 g a.i./ha. Based on the data presented and consistent results from other disease claims, an interval of 7–10 days can be supported.

None of the trials tested the proposed application rates of 100 or 150 g a.i./ha; however, the 125 g a.i./ha rate provided very good control of the disease on both the leaves and fruits. Therefore, without further efficacy data to demonstrate otherwise, the 125 g a.i./ha rate can be supported.

5.1.1.8 Control of Late Blight (*Phytophthora infestans*) on Field Tomato, Tomatillo and Greenhouse Tomato

A total of eight tomato late blight trials were submitted for review. Of these, four were not assessed for efficacy due to low disease pressures, assessment of the wrong disease (early blight), or occurrence of confounding environmental factors during the study that made the results biased (researcher's opinion). However, these studies were assessed for phytotoxicity. The remaining four trials were conducted between 2002 and 2004 in the United States (Florida, California). Revus Fungicide was tested at 100, 125 or 150 g a.i./ha, applied alone or with an adjuvant, or treatments were set up to assess application intervals. Between 3 and 8 consecutive applications were made at 7-, 10- or 14-day intervals. Most, but not all, trials were statistically analyzed.

Results were consistent across most trials, showing that Revus Fungicide applied between 100 and 150 g a.i./ha resulted in good control of tomato late blight severity throughout the growing season and under increasing disease pressures. The data showed that under low to moderate disease pressures, the 100 g a.i./ha rate provided acceptable disease severity control when applied at 7- to 10-day intervals; however, 14-day intervals were too long between applications for consistent control. Under high disease pressures, the 150 g a.i./ha rate provided greater levels of disease control compared to the 100 g a.i./ha rate, and again, more frequent applications (7- and 10-day intervals) resulted in lower disease severity compared to a 14-day application interval. With respect to adjuvants, Revus Fungicide was tested with various non-ionic and organosilicone surfactants. Results showed a general increase in efficacy when any type of surfactant was used; however the increases were mainly numerical. Due to a lack of statistical analysis, it is unknown whether the differences were significant. In general, Revus Fungicide performed at levels similar to the commercial standards tested in the trials.

5.1.1.9 Control of Late Blight (*Phytophthora infestans*) on Root and Tuber Vegetables (Tuberous and Corm subgroup)

A total of nine potato late blight trials were submitted for review. Studies were conducted between 2002 and 2005 in the United States (New York, Michigan, Florida, Pennsylvania), and all had medium to high disease pressures throughout the study period. Revus Fungicide was tested at 100, 125 or 150 g a.i./ha, applied alone or with an adjuvant, or treatments were set up to assess application intervals. Between 3 and 9 consecutive applications were made at 3- to 14-day intervals. Disease severity, AUDPC or yield, was assessed.

Results showed that in all trials except for one, an application of Revus Fungicide at 100, 125 or 150 g a.i./ha provided good to excellent control of late blight disease severity compared to the untreated control, with the higher rate of 150 providing slightly greater control than the 100 g a.i./ha rate. The greatest increases in disease severity control were associated with the

increased frequency and initial timing of applications. The proposed rates of 100–150 g a.i./ha were supported. A greater number of applications made more frequently (i.e. 7-day intervals) resulted in notably greater disease control compared to the 14-day application interval. The 10-day interval was similar to the 7-day with respect to disease control. Therefore, a 7- to 10-day application interval was supported. With respect to the application of Revus Fungicide with or without an adjuvant, trials showed a consistent trend that applications of Revus Fungicide with an adjuvant, notably Activator 90 at 0.125–0.25% v/v and Silwet L77 at 0.1 v/v, increased efficacy when compared to Revus Fungicide applied alone.

Crop Grouping

The registration of Revus Fungicide was requested for the whole Root and Tuber Vegetables crop group. Since only data on potatoes were submitted, additional data are required to extrapolate the claim to the whole crop group. Therefore, only control on potatoes can be supported.

5.1.1.10 Control of Downy Mildew (*Bremia lactucae*) on Leafy Vegetables (Field Lettuce, Leaf and Head Lettuce, Spinach) and Greenhouse Lettuce

A total of nine studies conducted on head lettuce (six trials), leaf lettuce (two trials) and romaine lettuce (one trial), were submitted for review. All trials were conducted in 2001, 2002, 2004, 2005 or 2006 in either Florida or California. Disease pressures in the studies ranged from very low (2.5% disease severity) to very high (80% disease severity). Revus Fungicide was tested at 75, 100, 125 or 150 g a.i./ha, applied alone or with an adjuvant, or treatments were set up to assess application intervals. Between 2 and 6 consecutive applications of Revus Fungicide were made at 5- to 12-day intervals. Disease severity, disease incidence, and/or AUDPC were assessed.

Results were consistent across all trials, where an application of Revus Fungicide at any rate significantly reduced the level of disease severity compared to the untreated check treatment under moderate and high disease pressures. When comparing across all rates, the low rate of 75 g a.i./ha did not provide as good control as the 100 g a.i./ha rate; therefore, the 100 g a.i./ha rate is considered the lowest effective rate. When comparing the 100 to the 150 g a.i./ha rate, there were no significant differences in disease severity reported. Application intervals of between 7 and 11 days demonstrated good control; therefore, this interval can be supported. No phytotoxicity was reported in any of the trials.

Crop Grouping

Three crops were tested in the trials: head lettuce, leaf lettuce and Romaine lettuce. Since the efficacy results were consistent across all of the studies, and there were no reports of phytotoxicity, they can all be supported. This claim can also be extended to include spinach, given this crop is also susceptible to the pathogen.

5.1.1.11 Control of Blue Mould (*Peronospora effusa*) on Leafy Vegetables (Field Lettuce, Leaf and Head Lettuce, Spinach) and Greenhouse Lettuce

Within the leafy vegetables group, *Peronospora effusa* is responsible for downy mildew (also known as blue mould) on spinach and lettuce only. Two studies conducted on spinach in California in 2004 and 2005 were submitted for review. Revus Fungicide was applied at 100 g a.i./ha between 3 and 6 times per season, at application intervals ranging from 8 to 12 days. In both trials, Revus Fungicide was applied alone or with Activator 90. Disease pressures were considered to be moderate to high.

Results in both trials showed that there was excellent efficacy of Revus Fungicide against blue mould of spinach, when applied at 100 g a.i./ha. The application interval of 8 to 12 days also resulted in good disease control. There were no statistically significant differences between the two Revus Fungicide treatments (with and without the adjuvant); however, there were numerical differences, with the presence of the adjuvant increasing the level of disease severity control. No phytotoxicity was reported in either study.

Although the studies did not directly test lettuce, this crop is susceptible to *Peronospora effusa* as well, and the claim can be extrapolated to include lettuce. No other leafy vegetables (head lettuce, leaf lettuce, etc) are susceptible to this pathogen.

5.1.1.12 Aerial Application

Based on evidence from similar formulations, data indicated that a flowable formulation with the same mode of action provided a similar level of disease control when applied aerially or by ground. Therefore, no unacceptable loss of efficacy is expected when Revus Fungicide is applied by aerial application. For aerial application, a minimum carrier volume of 45 L was specified on the product label.

5.1.1.13 Revus Fungicide Tank Mix with Bravo Weatherstik

A tank mix of Revus Fungicide with Bravo 500 Agricultural Fungicide was requested for all crops and diseases on the proposed Revus Fungicide label, to either reduce the possibility of resistance developing or to broaden the spectrum of diseases controlled or suppressed. Not all crops, however, are currently listed on the Bravo 500 Agricultural Fungicide label.

The only Revus Fungicide rate tested was 100 g a.i./ha + 1000 g a.i./ha Bravo Weatherstik. Bravo Weatherstik (720 g chlorothalonil/L) is an American product with a different guarantee than the same product registered in Canada, Bravo 500 Agricultural Fungicide. The registered rates for Bravo 500 Agricultural Fungicide vary from 0.6 to 2.0 kg a.i./ha depending on the crop and disease. Based on the similarities of these two Bravo products, it is expected that the Canadian formulation will perform in a similar manner.

Tank mix data were submitted on the following crops: Chinese broccoli (downy mildew), potatoes (late blight), tomatoes (late blight); and on the following cucurbits: cucumbers, winter squash, and pumpkins (downy mildew). Results indicate that Revus Fungicide can be tank-mixed with Bravo 500 Agricultural Fungicide, that there are no incompatibility issues, and that no unacceptable loss of efficacy occurs as a result of tank mixing these two products.

5.1.1.14 Maximum Number of Season Applications

Based on the fungicide Group 40 recommendations from the Fungicide Resistance Action Committee (FRAC), a seasonal maximum of four applications per season may be made, regardless of whether Revus Fungicide is applied at 100 or 150 g a.i./ha. Refer to Section 5.5.3 for further discussion.

5.2 Phytotoxicity to Host Plants

When Revus Fungicide was applied alone, there were no reports of unacceptable phytotoxicity to the crops tested in any of the trials submitted, with the exception of greenhouse cucumbers. This includes when a greater number of applications were made sequentially to a crop (up to 10), or when rates above 150 g a.i./ha were tested. Where phytotoxicity was reported in a trial, it occurred after tank-mixing with an organo-silicate adjuvant, and was considered to be an isolated case because it was not reported in other studies on similar crops. Therefore, based on this evidence, it is believed that Revus Fungicide is not phytotoxic to most crops when applied according to the proposed use pattern. For greenhouse cucumbers, the registrant supplied the following label wording to mitigate possible adverse effects for this crop and use.

Application of REVUS may result in injury on some cucumber varieties grown under cover, resulting in potential discolouration and necrotic spots on the fruit surface. Since not all cucumber varieties have been tested for tolerance to REVUS, first use of REVUS should be limited to a small area of each variety to confirm tolerance prior to adoption as a general production practice.

5.3 Impact on Succeeding Crops

Not assessed.

5.4 Economics

Not assessed.

5.5 Sustainability

5.5.1 Survey of Alternatives

Refer to Appendix I, Table 16 for a summary of the active ingredients currently registered for the same uses as Revus Fungicide.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

The use of Revus Fungicide is compatible with current integrated pest management practices and production practices.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Based on reports from the FRAC, sensitivity monitoring studies have suggested that populations of *Phytophthora infestans*, the causative pathogen of potato and tomato late blight, have not developed resistance to mandipropamid. However, certain isolates of *Plasmopara viticola*, the causative pathogen for downy mildew of grape, have been found to be simultaneously resistant to all group 40 active ingredients. Therefore, resistance management practices are required when using Revus Fungicide on grapes for control of downy mildew, and are highly recommended when using on other labelled diseases and crops. It is recommended to follow the FRAC CAA guidelines for resistance management when using Revus Fungicide. With regards to other oomycete (*Peronosporomycete*) pathogens, which cause downy mildew on various crops, FRAC considers these to be high risk pathogens, and despite a lack of resistance being detected in the field for CAA active ingredients, resistance management precautions are recommended.

Specific Resistance Management Practices for the use of Group 40 Fungicides on *Plasmopara viticola*:

- Apply a maximum of four CAA sprays during one crop cycle
- Apply CAA fungicides always in mixture with effective partners such as multi-sites or other non cross-resistant fungicides
- An effective partner for a CAA fungicide is one that provides satisfactory disease control when used alone at the mixture rate

Specific Resistance Management Practices for Group 40 Fungicides on *Phytophthora infestans*:

- Use of CAA fungicides limited to a maximum of 50% of all intended applications for *Phytophthora* control
- Alternation with other modes of action should be considered

Specific Resistance Management Practices for Group 40 Fungicides on other oomycete (*Peronosporomycete*) pathogens:

- Use of CAA fungicides limited to a maximum of 50% of all intended applications for *Phytophthora* control
- Alternation with other modes of action should be considered

Currently, there are no other products registered for control or suppression of phytophthora blight on peppers, including Bravo 500 Agricultural Fungicide. Therefore, it is not possible to tank-mix Revus Fungicide for the purposes of resistance management, or to alternate with other products. For this reason, and following the CAA recommendations from FRAC, only one application of Revus Fungicide may be made to pepper transplants for the suppression of phytophthora blight.

5.5.4 Contribution to Risk Reduction and Sustainability

Revus Fungicide offers a new fungicide chemistry to Canadian growers for use on leafy vegetables, grapes, tomatoes, cucurbits, bulb vegetables, and Brassica head and stem crops. It is currently the only fungicide registered in Canada for suppression of phytophthora blight on peppers. Revus Fungicide can be tank-mixed with Bravo 500 Agricultural Fungicide for resistance management, or to increase the disease spectrum on crops that are registered on both product labels.

6.0 Pest Control Product Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is the virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, mandipropamid was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of mandipropamid were also considered, including transformation products formed in the environment and contaminants and formulants in the technical product and end-use product. Mandipropamid and its transformation products were evaluated against the following Track 1 criteria: persistence in soil ≥ 182 days, persistence in water ≥ 182 days, persistence in sediment ≥ 365 days, persistence in air ≥ 2 days, bioaccumulation $\log K_{ow} \geq 5$ or BCF ≥ 5000 (or bioaccumulation factor ≥ 5000). In order for mandipropamid or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern. The PMRA has reached the following conclusions.

Mandipropamid does not meet the Track 1 criterion for persistence, as its half-life values in water (2.1 to 14.5 days), soil (20 to 86 days), and sediment (15.3 to 20.6 days) are below the Track 1 criteria. Mandipropamid does not meet the Track 1 criterion for persistence in air because volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on its vapour pressure ($<7.05 \times 10^{-9}$ mm Hg) and Henry's law constant ($<9.1 \times 10^{-10}$ atm m³/mole). Mandipropamid does not meet the Track 1 criterion for bioaccumulation, as its bioconcentration factor (BCF = 8.8–10 for edible tissue) is below the Track 1 criterion. Therefore, mandipropamid does not meet the Track 1 criteria, and is not considered a Track 1 substance.

Mandipropamid does not form any transformation products that meet the Track 1 criteria.

There are no Track 1 contaminants in the technical product.

The end-use product, Revus Fungicide, contains a formulant contaminated with the Track 1 substances (hexa- to octa-dioxins and penta- to octa-furans) identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3 Contaminants of Health or Environmental Concern. The PMRA is managing the presence of these contaminants in accordance with the Agency's strategy to prevent or minimize releases, with the ultimate goal of virtual elimination as described in *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations including the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol); and the *PMRA Formulants Policy* as described in the PMRA Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern is maintained and used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern consists of three parts:

- Part 1: Formulants of Health or Environmental Concern;
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions; and
- Part 3: Contaminants of Health or Environmental Concern.

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances and are considered in section 6.1. The following assessment refers to the formulants and contaminants in Part 1 and Part 2 of the list.

Technical grade Mandipropamid and the end-use product Revus Fungicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for mandipropamid is adequate to define the majority of toxic effects that may result from exposure to mandipropamid. In subchronic and chronic studies on laboratory animals, the primary target was the liver along with decreased body-weight gain. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Mandipropamid is not considered to be a neurotoxicant. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The residue definition for enforcement purposes is mandipropamid in primary crops, rotational crops and animal commodities. For risk-assessment purposes, the residue definition is mandipropamid in primary crops (except root and tuber vegetables), rotational crops and animal commodities; and mandipropamid and the metabolite SYN 500003 in root and tuber vegetables.

The proposed use of mandipropamid on Brassica vegetables, lettuce (leaf and head), spinach, bulb vegetables, cucurbits, peppers, field tomato (tomatillo), grapes, potatoes, greenhouse vegetables (lettuce, tomato and cucumber) and including the importation of okra, fruiting vegetables, leafy vegetables (except Brassica) and tuberous and corm vegetables does not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

Sufficient crop residue data have been reviewed to recommend maximum residue limits, both domestic and import, to protect human health. The PMRA recommends that the following maximum residue limits be specified for residues of mandipropamid in and on Leafy Brassica greens (Crop Subgroup 5B) (25 ppm); Leafy vegetables, except Brassica (Crop Group 4) (20 ppm); Green onion subgroup (Crop Subgroup 3-07B) (4.0 ppm); Head and stem Brassica (Crop Subgroup 5A), raisins (3.0 ppm); Grapes (1.4 ppm); Fruiting vegetables (Crop Group 8), okra (1.0 ppm); Cucurbit vegetables (Crop Group 9) (0.6 ppm); Bulb onion subgroup (Crop Subgroup 3-07A) (0.05 ppm); and Tuberous and corm vegetables (Crop Subgroup 1C) (0.01 ppm).

Mixers, loaders and applicators handling Revus Fungicide and workers re-entering areas treated with Revus Fungicide are not expected to be exposed to levels of mandipropamid that will result in an unacceptable risk when Revus Fungicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

7.2 Environmental Risk

The use of Revus Fungicide is not expected to pose a risk to terrestrial or aquatic organisms when used according to label directions. Standard environmental label statements must be added or updated on the product labels as precautions.

7.3 Value

Sufficient evidence of efficacy was provided to support the use of Revus Fungicide to control or suppress various diseases on field or greenhouse vegetable crops, grapes, and potatoes. The lower proposed rate was confirmed as the lowest effective rate. Revus Fungicide offers a new fungicide chemistry to Canadian growers for use on leafy vegetables, grapes, tomatoes, cucurbits, bulb vegetables, and Brassica head and stem crops. It is currently the only fungicide registered in Canada for suppression of phytophthora blight on peppers. Revus Fungicide can be tank-mixed with Bravo 500 Agricultural Fungicide for resistance management or to increase the disease spectrum on crops that are registered on both product labels.

A summary of the proposed and accepted uses for Revus Fungicide is presented in Appendix I, Table 17.

7.4 Unsupported Uses

Certain uses originally proposed with this application are not supported by the PMRA either because value has not been adequately demonstrated or due to unacceptable risk. Unsupported uses are listed below in Table 7.4.1.

Table 7.4.1 Use Claims Proposed that were Unsupported

Crop	Disease	Reason for Not Supporting the Claim
Cucurbits: Cantaloupe, chayote, Chinese-waxgourd, field cucumber, gourds, honeydew, melons <i>Momordica</i> spp. (bitter melon, balsam apple), muskmelon, watermelon, pumpkin, squash, zucchini, including cultivars and/or hybrids of these Greenhouse cucumbers	Phytophthora blight (<i>Phytophthora capsici</i>)	No data on the pathogen / disease for any crop within this crop group were submitted. Extrapolation for the conditionally supported claim for the same disease on peppers could not be made as the data were very limited.
Fruiting Vegetables Crop Group: Eggplant, okra, ground cherry, pepino	Downy mildew (<i>Peronospora tabacina</i>)	While peppers (Bell and non-Bell) were conditionally supported based on very limited data, insufficient data were submitted to support a crop group claim.
Root and Tuber Vegetables Tuberous and Corm subgroup: Arracacha, arrowroot, Chinese and Jerusalem artichoke, burdock, canna, edible bitter and sweet cassava, chayote (root), chufa, dasheen (Taro), ginger, leren, potato, sweet potato, tanier, turmeric, yam (bean), yam (true)	Late blight (<i>Phytophthora infestans</i>)	Only data on potatoes were submitted, and the applicant did not provide evidence that late blight is a problem on the remaining crops listed; therefore, insufficient data were submitted for a crop group claim.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of the technical grade active ingredient Mandipropamid Technical Fungicide and the end-use product Revus Fungicide to control downy mildew on Brassica crops, bulb vegetables, grapes, leafy vegetables (including field and greenhouse, not transplants for the field, and blue mould on spinach); late blight on tomatoes (including field and greenhouse, not transplants for the field), tomatillos and potatoes; and suppression of phytophthora blight on peppers (Bell and non-Bell peppers to be treated in the greenhouse and immediately transplanted to the field), and suppression of downy mildew on cucurbits (including field and greenhouse, not transplants for the field).

An evaluation of current scientific data from the applicant has resulted in the determination that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been determined to be acceptable when all risk-reduction measures are followed, as a condition of these registrations, the additional scientific information (listed below) is being requested from the applicant as a result of this evaluation. For more details, refer to the Section 12 Notice associated with these conditional registrations.

Chemistry

- Analytical data from at least five batches of technical grade active ingredient representing full-scale production, once commercial production has commenced at the manufacturing site.
- Analytical methods for the transformation products of mandipropamid in water and sediment.

Human Health

- For enforcement purposes, a confirmatory method or interference study for RAM 415/01.
- Final study report demonstrating the storage stability of analytical standards
- Freezer storage stability study for residues of SYN 500003 in potato tubers and potato processed fractions for up to 32 months of frozen storage.
- Greenhouse lettuce trials conducted according to the approved Revus Fungicide label rate.

Value

- Confirmatory efficacy trials are required assessing whether the higher rate of Revus Fungicide (150 g a.i./ha) is required for control of downy mildew (*Peronospora destructor*) on green (bunching) onions, leeks and Welch onions. Efficacy data is required within two years of a conditional registration being granted.
- Confirmatory efficacy trials are required assessing Revus Fungicide for control of downy mildew (*Peronospora parasitica*) on crops within the Brassica leafy greens sub-group.
- Confirmatory efficacy trials are required assessing Revus Fungicide for suppression of phytophthora blight (*Phytophthora capsici*) on peppers (Bell and non-Bell), as well as all other crops within the fruiting vegetables crop group.

NOTE: The PMRA will publish a Consultation Document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

List of Abbreviations

µg	micrograms
µl	microlitre
ADI	acceptable daily intake
a.i.	active ingredient
AR	applied radioactivity
ARfD	acute reference dose
atm	atmosphere
AUDPC	area under the disease progress curve
BCF	bioaccumulation factor
bw	body weight
CAA	carboxylic acid amide
CAF	composite assessment factor
CAS	Chemical Abstracts Service
cm	centimetres
C _{max}	maximum concentration
COEX	co-extrusion
d	day(s)
DALA	days after last application
DT ₅₀	dissipation time 50% (the dose required to observe a 50% decline in the test population)
DT ₉₀	dissipation time 90% (the dose required to observe a 90% decline in the test population)
dw	dry weight
E _b C ₅₀	50% effective concentration for biomass
EC	emulsifiable concentrate
EC ₂₅	effective concentration on 25% of the population
EC ₅₀	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure
E _r C ₅₀	50% effective concentration for reproduction
EUP	end-use product
F ₁	first filial generation
F ₂	second filial generation
FIR	food ingestion rate
FOB	functional observational battery
FRAC	Fungicide Resistance Action Committee
g	gram
GUS	groundwater ubiquity score
h	hour(s)
ha	hectare(s)
HAFT	highest average field trial
HDPE	high-density polyethylene
Hg	mercury
HPLC	high performance liquid chromatography

IUPAC	International Union of Pure and Applied Chemistry
i.v.	intravenous
kg	kilogram
K_{foc}	Freundlich organic-carbon partition coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	<i>n</i> -octanol–water partition coefficient
L	litre
LC/MS/MS	Liquid chromatography with tandem mass spectrometry
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOQ	limit of quantitation
LR ₅₀	lethal rate 50%
LSC	liquid scintillation counting
m	metre
mg	milligram
mL	millilitre
mm	millimetre(s)
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
MS	mass spectrometry
MTD	maximum tolerated dose
N/A	not applicable
NAFTA	North American Free Trade Agreement
NER	non-extractable residues
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
P	parental generation
Pa	pascal
PBI	plantback interval
PET	polyethylene terephthalate
pH	–log ₁₀ hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
pK _a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RAC	raw agricultural commodity
RAM	residue analytical method
RQ	risk quotient
SC	soluble concentrate
SF	safety factor
t _{1/2}	half-life

TGAI	technical grade active ingredient
TLC	thin layer chromatography
T _{max}	maximum time
TRR	total radioactive residue
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
vp	vapour pressure
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference (PMRA #)
Soil	—	Active	HPLC-MS-MS ¹	0.5 µg/kg		1348290 1348289
	—	CGA-380778				
Saltwater	—	Active	HPLC-UV	0.05 mg a.i./L		1348291
Plant	RAM 415/01	Mandipropamid	Data Gathering and Enforcement LC-MS/MS	0.01 ppm	Cucumber, grape (fruit, wine, raisins, dry pomace), leeks, melon (peel and flesh), onion, oranges, sweet pepper, potatoes, rape seed, spinach, tomato (fruit, juice and purée) and wheat (straw)	1386771 1348173 1348174 1348284
	GRM001.01.B	SYN 500003	Data Gathering LC-MS/MS	0.005 ppm	Potato (tubers, chips, granules/flakes and peel)	1457579

¹ Transitions monitored: mandipropamid 412.1 • 327.9; CGA-380778 374.1 • 327.9

Table 2 Acute Toxicity of Mandipropamid Technical Fungicide and Its Associated End-use Product (Revus Fungicide)

Study Type	Species	Result	Comment	Reference (PMRA #)
Acute Toxicity of Mandipropamid (Technical)				
Oral (up and down)	Rat	LD ₅₀ >5000 mg/kg bw	Low toxicity	1348240
Dermal	Rat	LD ₅₀ >5050 mg/kg bw	Low toxicity	1348241
Inhalation	Rat	LC ₅₀ >5.19 mg/L	Low toxicity	1348242
Skin irritation	Rabbit	Positive	Minimally irritating	1348243
Eye irritation	Rabbit	Positive	Minimally irritating	1348244
Skin sensitization	Guinea Pig	Negative	Not a dermal sensitizer	1348245
Skin sensitization	Mouse	Stimulation Index <3 Negative	Not a dermal sensitizer	1348246
Acute Toxicity of End-Use Product – Revus Fungicide (23.3% mandipropamid)				
Oral	Rat	LD ₅₀ >5000 mg/kg bw	Low toxicity	1348157
Dermal	Rat	LD ₅₀ >5000 mg/kg bw	Low toxicity	1348158
Inhalation	Rat	LC ₅₀ >4.89 mg/L	Low toxicity	1348159
Skin irritation	Rabbit	Positive	Minimally irritating	1348160
Eye irritation	Rabbit	Positive	Minimally irritating	1348161
Skin sensitization	Guinea Pig	Negative	Not a dermal sensitizer	1348162
Acute Toxicity of SYN 500003 impurity (<0.1%)				
Oral	Rat	LD ₅₀ = 1049 mg/kg bw	Moderate toxicity	1457538

Table 3 Toxicity Profile of Mandipropamid Technical Fungicide

Study Type	Species	Results* (mg/kg/day in M/F)	Reference (PMRA #)
14-day dermal	Rat	Effect levels not established, given this was a range-finding study. Slight dermal irritation (erythema, edema and scabs) were observed at 250 mg/kg bw/day.	1348256
28-day dermal irritation	Rat	Dermal irritation: NOAEL: 1000 mg/kg bw/day LOAEL: Not established	1348251
28-day dietary	Mouse	Effect levels not established, given this was a range-finding study. The following effects were noted at a dose level of 319/378 mg/kg bw/day (♂, ♀): decreased body weight (♀) and body-weight gain (♀) and increased liver weights (♀).	1348253
90-day dietary	Mouse	NOAEL: 248/316 mg/kg bw/day (♂, ♀) LOAEL: 624/800 mg/kg bw/day (♂, ♀), based on decreased body weight and body-weight gain.	1348247

Study Type	Species	Results ^a (mg/kg/day in M/F)	Reference (PMRA #)
28-day gavage	Rat	Effect levels not established, given this was a range-finding study. No compound-related effects were observed on measured parameters.	1457528
28-day dietary	Rat	Effect levels were not established, given this was a range-finding study. The following effects were noted at a dose level of 135/121 mg/kg bw/day (♂, ♀): decreased food consumption (♂, ♀) and overall body-weight gain (♂).	1348252
90-day dietary	Rat	NOAEL: 41/45 mg/kg bw/day (♂, ♀) LOAEL: 260 mg/kg bw/day (♂/♀), based on decreased body weight and body-weight gain and decreased food efficiency (♂).	1348248
Preliminary oral toxicity comparing capsule and dietary administration	Dog	Effects were not established, given this was a supplemental study. Effects seen with capsule administration included increased alkaline phosphatase, alanineamino transferase and absolute and relative liver weight and slightly reduced periportal glycogen. Effects seen with dietary administration included decreased leukocytes and neutrophils (♂), increased alkaline phosphatase (♀) and absolute and relative liver weight (♀), slight brown pigmentation of the liver, minimal single cell necrosis in the liver (♀) and slightly reduced peripotal glycogen.	1348255
6 week preliminary capsule	Dog	Effects were not established, given this was a range-finding study. The following effects were noted at a dose level of 100 mg/kg bw/day: increased alkaline phosphatase and liver weights (♀), hepatocyte pigmentation (consistent with porphyrin) and pigmentation of the Kupffer cells (♂).	1348254
90-day dietary	Dog	NOAEL: 100 mg/kg bw/day LOAEL: 400 mg/kg bw/day, based on increased cholesterol, alkaline phosphatase, alanine transaminase and liver weights.	1348249
One-year capsule	Dog	NOAEL: 5 mg/kg bw/day (♂/♀) LOAEL: 40 mg/kg bw/day (♂/♀), based on minimal pigmentation (porphyrin) in the liver.	1348250
Carcinogenicity (18-month dietary)	Mouse	NOAEL: 55/68 mg/kg bw/day (♂/♀) LOAEL: 222.7/284.6 mg/kg bw/day (♂/♀), based on decreased body weight and food efficiency (♂).	1348257
Chronic / Carcinogenicity (Two-year dietary)	Rat	NOAEL: 15.27/17.6 mg/kg bw/day (♂/♀) LOAEL: 61.3/69.7 mg/kg bw/day (♂/♀), based on decrease body weight (♂), body-weight gain (♂) and food efficiency (♂), increased incidence of roughened kidney surface (♂) and increased severity of renal osteodystrophia fibrosa (♂) and severiyparathyriod hyperplasia.	1348258

Study Type	Species	Results ^a (mg/kg/day in M/F)	Reference (PMRA #)
One-generation reproduction	Rat	Effects were not established, given this was a supplemental study. The following effects were noted at 144.9/145.0 mg/kg bw/day (♂/♀): increased food consumption (♂) and decreased food efficiency premating (♂).	1348279
Two-generation reproduction	Rat	Parental toxicity: NOAEL: 22.9/24.5 mg/kg bw/day (♂/♀) LOAEL: 146.3/148.2 mg/kg bw/day (♂/♀), based on decreased body weight (F1 ♂) and body-weight gains (F1 ♂) during premating and increased absolute and adjusted liver weight (P ♂, P ♀ and F1 ♀) Offspring toxicity: NOAEL: 22.9/24.5 mg/kg bw/day (♂/♀) LOAEL: 146.3/148.2 mg/kg bw/day (♂/♀), based on decreased body weight (F1 and F2b), increased adjusted liver weights (F1, F2a and F2 b pups), increased absolute liver weights (F2a ♀) and increased time to preputial separation (F1 ♂). Reproductive toxicity: NOAEL: 146.3/148.2 mg/kg bw/day (♂/♀) LOAEL: Not established	1348259
Developmental toxicity (range-finding)	Rat	Effects were not established, given this was a range-finding study. Decreased total bilirubin was noted at 250 mg/kg bw/day.	1348277
Developmental toxicity (range-finding)	Rat	Effects were not established, given this was a range-finding study. No compound-related effects were observed on measured parameters.	1348274
Developmental toxicity	Rat	Maternal: NOAEL: 1000 mg/kg bw/day LOAEL: Not established Developmental: NOAEL: 1000 mg/kg bw/day LOAEL: Not established	1348260
Developmental toxicity (range-finding)	Rabbit	Effects were not established, given this was a range-finding study. No compound-related effects were observed on measured parameters.	1348275
Developmental toxicity (range-finding)	Rabbit	Effects were not established, given this was a range-finding study. No compound-related effects were observed on measured parameters.	1348276

Study Type	Species	Results ^a (mg/kg/day in M/F)	Reference (PMRA #)
Developmental toxicity	Rabbit	Maternal: NOAEL: 1000 mg/kg bw/day LOAEL: Not established Developmental: NOAEL: 1000 mg/kg bw/day LOAEL: Not established	1348261
Reverse gene mutation assay	<i>Salmonella tryphimurium</i> strains TA98, TA 100, TA 1535, TA 1537, <i>E. Coli</i> WP2P and WP2PuvrA	Negative	1348262
Gene mutations in mammalian cells in vitro	Mouse lymphoma Cells (TK ^{+/+} locus)	Negative	1348263
In vitro unscheduled DNA synthesis	Primary rat hepatocytes from male rats	Negative	1348266
In vitro mammalian chromosomal aberration	Human lymphocytes	Negative	1348265
In vivo mammalian cytogenetics	Male and female rats	Negative	1348264
Genotoxicity of impurities			
Reverse gene mutation assay SYN 500003	<i>Salmonella tryphimurium</i> strains TA98, TA 100, TA 1535, TA 1537, <i>E. coli</i> WP2P and WP2PuvrA	Negative	1457539
Gene mutations in mammalian cells in vitro SYN 545038	<i>Salmonella tryphimurium</i> strains TA98, TA 100, TA 1535, TA 1537, <i>E. Coli</i> WP2P and WP2PuvrA	Positive in the presence of metabolic activation	1457540

Neurotoxicity			
Primary acute neurotoxicity (gavage)	Rat	Effects were not established, since this was a range-finding study. No treatment related effects were noted in the FOB. Decreased mean body weight (♂) was noted at 2000 mg/kg bw.	446510
Acute neurotoxicity (gavage)	Rat	Neurotoxicity: NOAEL: >2000 mg/kg bw/day LOAEL: Not established Systemic: NOAEL: >2000 mg/kg bw/day LOAEL: Not established	1348271
Subchronic neurotoxicity (dietary)	Rat	Neurotoxicity: NOAEL: 192.5/206.7 mg/kg bw/day LOAEL: Not established Systemic: NOAEL: 37.3/41.0 mg/kg bw/day (♂/♀) LOAEL: 192.5/206.7 mg/kg bw/day (♂/♀), based on decreased body weight (♂), body-weight gain (♂) and food efficiency (♂)	1452941
Special studies			
Single high dose oral toxicity	Mouse	Effect levels not established, since this study was considered supplemental. The following effects were noted at 5000 mg/kg bw/day: increased cholesterol (12 h ♂, 12 and 24 h ♀), total bilirubin (24 h) and absolute, adjusted and relative body weight at ≥12 h post dosing.	1457531
Single high dose oral toxicity	Rat	Effect levels not established, since this study was considered supplemental. The following effects were noted at 5000 mg/kg bw/day: increased absolute, adjusted and relative liver weight, mitosis in the liver and periportal eosinophilia in the liver at 12 and 48 h but not at 24 h (♂).	1457532
Single oral dose toxicity Propargyl alcohol	Rat	Effect levels not established, since this study was considered supplemental. The purpose of this study was to characterize the effects on the liver after single oral dosing with propargyl alcohol and select doses for the repeat dose study.	1457537

Repeat (14-day) oral dose toxicity Propargyl alcohol	Rat	<p>Effect levels not established, since this study was considered supplemental. The purpose of this study was to characterize the effects on the liver after repeat oral dosing with propargyl alcohol and to compare the resulting liver effects to those caused by subchronic administration of mandipropamid.</p> <p>Conclusion: Propargyl alcohol and mandipropamid demonstrate similar liver effects. These effects include increased liver weights, induction of liver enzymes, histopathology and hepatocyte proliferation.</p>	1457536
28-day assessment of cell proliferation in mouse liver	Mouse	<p>Effect levels not established, since this study was considered supplemental. The purpose of this study was to identify the key biochemical and morphological changes associated with the mandipropamid-induced liver enlargement in the mouse.</p> <p>Conclusion: No cell proliferation was observed.</p>	1457529
Cell proliferation in female rat liver	Rat	<p>Effect levels not established, since this study was considered supplemental. The purpose of this study was to determine whether the liver enlargement in the rat was due to hepatocellular proliferation.</p> <p>Conclusion: No cell proliferation was observed.</p>	1457528
Effects on the rat liver (in vivo and in vitro)	Rat	<p>Effect levels not established, since this study was considered supplemental. The purpose of the in vivo studies was to characterize the biochemical and pathological changes occurring in rat liver following dietary administration of mandipropamid for up to 28 days in order to understand the basis of the liver growth. The purpose of the in vitro study was to investigate the metabolism of mandipropamid in order to establish which enzymes are involved in metabolite production.</p> <p>Conclusion: In the in vivo study, no cell proliferation was observed. The data from the in vitro study suggests that CYP2B1, CYP2B2 and/or CYP1A2 may participate in the biotransformation of mandipropamid.</p>	1457530

Metabolism	Rat	<p>Absorption: Mandipropamid is rapidly but moderately absorbed (approximately 67–74% at low dose and 30–45% at high dose, both at 48 h) following oral gavage dosing (3 or 300 mg/kg bw) in the rat. Absorption (as percent administered radioactivity) was decreased at the high dose suggesting saturation of the absorption kinetics.</p> <p>Repeated dietary dosing at levels of 100 to 5000 ppm did not demonstrate saturation of absorption. The T_{max} in blood at the low dose was 8.5 h in males and 4.5 h in females. At the high dose, the T_{max} was 24 h in males and 10 h in females.</p> <p>Distribution: The highest levels occurred in the liver and kidney followed by pancreas, plasma and blood. Combined, these tissues and organs accounted for less than 1% of the administered dose. There was no evidence of bioaccumulation.</p> <p>Excretion: Bile excretion accounted for a significant proportion of excretion with a wide range between sexes and dose levels. Urine was the least common route of excretion. Females frequently showed significantly greater urinary excretion than males due to the metabolite NOA 452422 glucuronide, which the males eliminated almost completely through bile and feces. Fecal excretion of radioactivity tended to be lower than bile excretion in males but not females. Excretion (88-99%) was virtually complete by 168 h.</p> <p>Metabolism: More than half the excreted product was mandipropamid glucuronide (mostly in urine for females and bile for males), with parent in urine, feces and bile, SYN 534133 in urine and bile, CGA 380778 (2-(4-Chloro-phenyl)-2-hydroxy-N-[2-(3-methoxy-4-prop-2-ynyloxy-phenyl)-ethyl]-acetamide) in the urine and feces and SYN 505503 glucuronide (2-(4-Chloro-phenyl)-N-[2-(3,4-dihydroxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide) and SYN 505504 glucuronide 2-(4-Chloro-phenyl)-N-2[2-(3,4-dihydroxy-phenyl)-ethyl]-2-hydroxy-acetamide) in the urine.</p>	1348267 1348268 1348269
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Metabolism	Dog	<p>Absorption: Recoveries of mandipropamid were ~75–103% of the administered dose following oral administration to dogs by gelatin capsule (100 or 800 mg/kg bw; 15 days) at 72 h. No significant differences in recovery were noted between single and repeat dosing and there were no sex differences. Recoveries of mandipropamid were ~69–87% following intravenous administration (3 mg/kg bw) to dogs at 72 h. After a 15-day washout and a single gelatin capsule dose (3 mg/kg bw), the recoveries were 87% of the administered dose in both sexes. The majority of the radioactivity was generally recovered during the first 24 h post-dosing. Absorbed mandipropamid was rapidly and extensively metabolized. There were no apparent differences in T_{max} in blood in the low (4–10 h) or high (6–10 h) dose groups after oral administration. After intravenous dosing, the T_{max} was 5.32 h in males and 3.17 h in females; these values decreased to 1 h in males and 3 h in females after the washout and single oral dose.</p> <p>In general, females took 1.7–2.5× longer to reach C_{max} than males, although these differences were not observed in repeat high dose and intravenously dosed groups. Some accumulation/saturation occurred with repeat 800 mg/kg bw dosing. Bioavailability of the oral dose was 44% for males and 78% for females. Doses of ≥ 100 mg/kg bw were poorly absorbed and absorption decreased with increasing dose levels, suggesting saturation of absorption processes. Repeated dosing did not appear to have an effect on the route or rate of metabolism in either sex but increased the number of urinary metabolites.</p> <p>Distribution: Not determined</p> <p>Excretion: The majority of the administered dose was eliminated in the feces. The presence of radioactivity in the feces of animals dosed intravenously indicated a substantial contribution via biliary excretion. The single dose 100 mg/kg bw females appeared to excrete more radioactivity in the urine than the males and the other orally dosed groups. Urine was also a major route of elimination in the intravenously dosed animals.</p> <p>Metabolism: Major metabolites were parent in feces, and NOA 458422 glucuronide, CGA 380778 glucuronide, NOA 458422 sulfate and Metabolite A (tentatively identified as O-glucuronide of NOA 446510) in urine. Minor metabolites included CGA 380775 glucuronide in feces and urine, NOA 458422 in feces and urine, CGA 380778 in feces and urine and SYN 505503 in feces. Others were present at lower concentrations. Note: Urine profiled at 6 h only.</p>	1457535
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^a Effects observed in males as well as females unless otherwise reported.

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Mandipropamid Technical Fungicide

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	UF/SF ¹ or Target MOE ²
Acute dietary	Not required			
	ARfD = not required			
Chronic dietary	NOAEL = 5	12-month capsule dog	– pigmentation in the liver (porphrin)	100
	ADI = 0.05			
Short-term dermal	NOAEL = 1000	28-day dermal rat	– limit dose with no treatment-related effects	100
Short-term to intermediate-term inhalation	NOAEL = 41	90-day dietary rat	– decreased body weight and body-weight gain and decreased food efficiency.	100
Short-term dermal	NOAEL = 1000	28-day dermal rat	– limit dose with no treatment-related effects	300
Long-term inhalation	NOAEL = 5	One-year dog	– porphyrin staining in the liver and increased liver enzymes	100

¹ Dietary scenarios

² Exposure scenarios

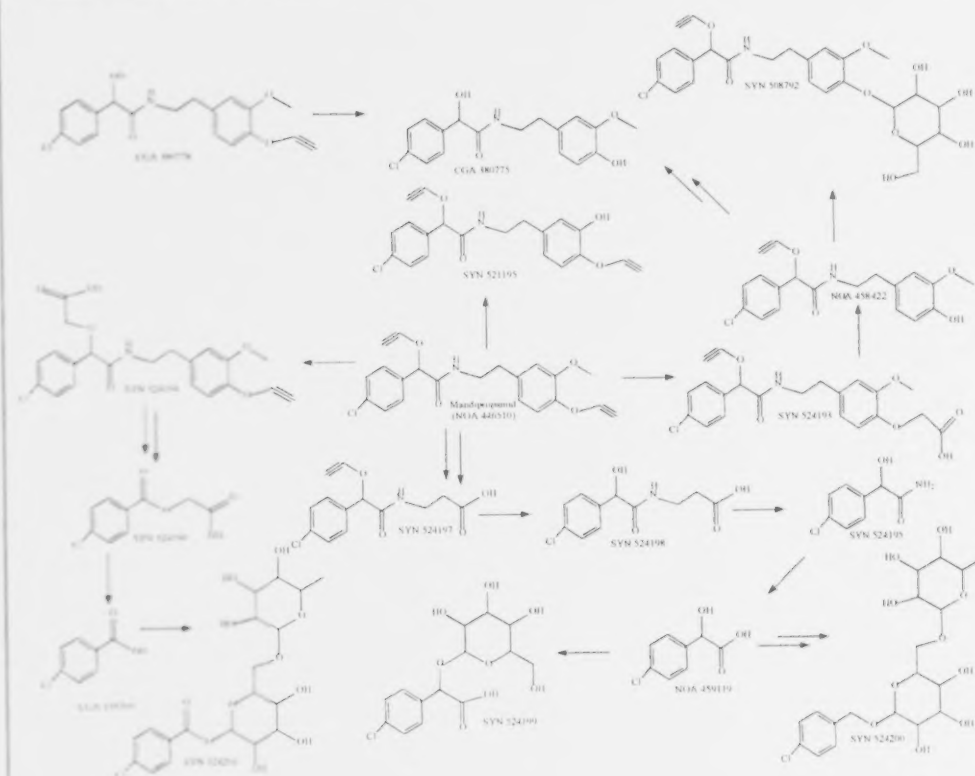
Table 5 Integrated Food Residue Chemistry Summary

Nature of the Residue in Crop – Grapes		PMRA #1348286	
Radiolabel Position	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]	
Test site	Field-grown grape vines.		
Treatment	Mandipropamid was applied to grape vines using a hand-held sprayer. The first application was made at BBCH 67 stage (70% flowerhoods fallen). All subsequent applications were made at 10- to 12-day re-treatment intervals. Residue data from the exaggerated treatment rates were used for metabolite characterization.		
Rate	Six sequential applications at 143 g a.i./ha (1st), 144 g a.i./ha (2nd), 143 g a.i./ha (3rd), 145 g a.i./ha (4th), 151 g a.i./ha (5th) and 150 g a.i./ha (6th) for a total of 876 g a.i./ha Exaggerated Treatment Rate Six foliar applications at 411 g a.i./ha (1st), 430 g a.i./ha (2nd), 417 g a.i./ha (3rd), 431 g a.i./ha (4th), 432 g a.i./ha (5th) and 435 g a.i./ha (6th) for a total of 2556 g a.i./ha.	Six sequential applications at 151 g a.i./ha (1st), 151 g a.i./ha (2nd), 147 g a.i./ha (3rd), 148 g a.i./ha (4th), 146 g a.i./ha (5th) and 151 g a.i./ha (6th) for a total of 894 g a.i./ha Exaggerated Treatment Rate Six foliar applications at 449 g a.i./ha (1st), 464 g a.i./ha (2nd), 440 g a.i./ha (3rd), 438 g a.i./ha (4th), 438 g a.i./ha (5th) and 421 g a.i./ha (6th) for a total of 2650 g a.i./ha.	
End-use product	Suspension concentrate (SC 250).		
Preharvest interval	0, 14 and 28 days after the final (6th) application. For the exaggerated treatment rate, samples were harvested at only 28 days after the final (6th) application		
Matrix	Radiolabel Position	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]
	Preharvest Interval (PHI) (days)	Total Radioactive Residue (TRR) (ppm)	Total Radioactive Residue (TRR) (ppm)
Grape fruit	Direct determination by combustion/liquid scintillation counting (LSC) (Summation of the wash analyzed by LSC and the washed grapes analyzed by combustion/LSC)		
	0	1.321	2.115
	14	1.333	1.029
	28	0.911	1.076
	28 (exaggerated treatment rate)	7.3197	4.401
	Indirect determination (Summation of the extractable and nonextractable radioactivity)		
	0	1.321	2.094
	14	1.32	1.036
	28	0.911	1.077
	28 (exaggerated treatment rate)	7.379	4.38

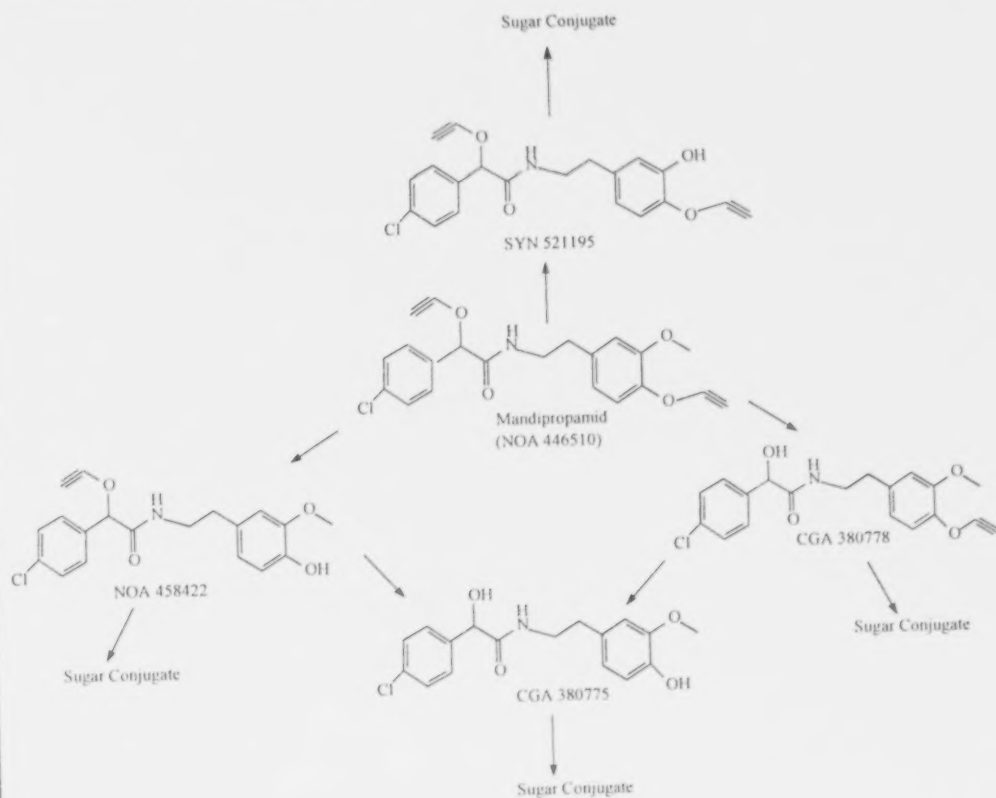
Grape leaves	Direct Determination by Combustion/LSC			
	0	59.25	66.955	
	14	48.649	59.036	
	28	29.451	35.609	
	28 (exaggerated treatment rate)	126.717	90.39	
	Indirect Determination (Summation of the Extractable and Nonextractable Radioactivity)			
	0	74.947	75.643	
	14	50.388	61.993	
	28	42.458	43.321	
	28 (exaggerated treatment rate)	122.54	122.789	
Metabolites Identified	Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position	[14C-Chloro-phenyl]	[14C-Methoxy-phneyl]	[14C-Chloro-phenyl]	[14C-Methoxy-phenyl]
Grape fruit	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778; CGA 380775; CGA 155705; SYN 524197; SYN 524195; SYN 508792; SYN 524200; SYN 524201; SYN 524193; SYN 524194; SYN 524196; NOA 459119; SYN 524198; SYN 524199	NOA 458422; CGA 380778; CGA 380775; CGA 155705; SYN 524197; SYN 508792; SYN 524193; SYN 524194; SYN 524196; NOA 459119; SYN 524198

Grape leaves	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778; CGA 380775; CGA 155705; SYN 524197; SYN 524195; SYN 508792; SYN 524200; SYN 524201; SYN 524193; SYN 524194; SYN 524196; NOA 459119; SYN 524198; SYN 524199	NOA 458422; CGA 380778; CGA 380775; CGA 155705; SYN 524197; SYN 508792; SYN 524193; SYN 524194; SYN 524196; NOA 459119; SYN 524198
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Proposed Metabolic Scheme in Grapes:

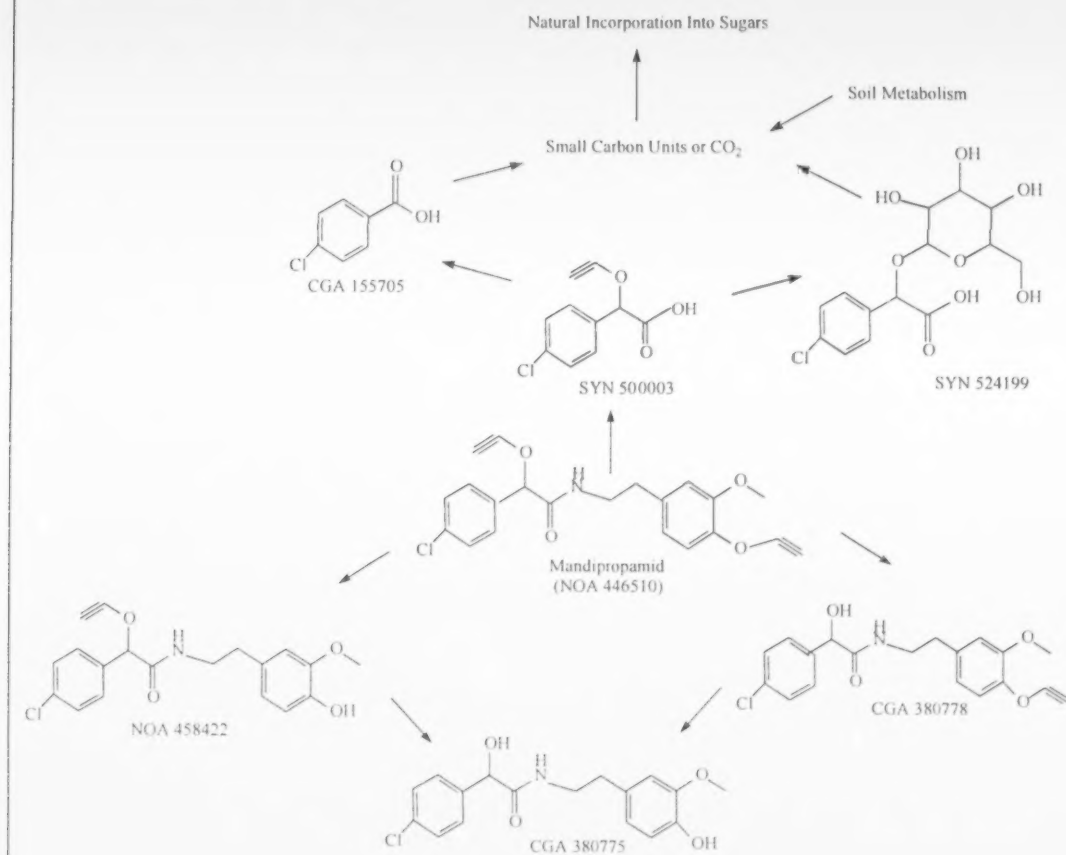


Nature of the Residue in Crop – Lettuce			PMRA #1348284	
Radiolabel Position	[Chlorophenyl-U-14C]		[Methoxyphenyl-U-14C]	
Test site	Outdoor conditions.			
Treatment	Two foliar spray application: 1st at the 9–11 leaf stage and the 2nd at the 10–12 leaf stage.			
Rate	136.0 g a.i./ha (1st application); 138.2 g a.i./ha (2nd application) for a total application rate of 274.2 g a.i./ha		155.5 (1st application); 159.5 g a.i./ha (2nd application) for a total application rate of 315.0 g a.i./ha.	
End-use product	Mandipropamid was formulated as a soluble concentrate.			
Preharvest interval	3 and 14 days after the 2nd (final) application.			
Matrix	Radiolabel Position	[Chlorophenyl-U- 14C]	[Methoxyphenyl-U-14C]	
	PHI (days)	TRR (ppm)	TRR (ppm)	
Lettuce	Direct determination by combustion/LSC			
	3	3.042	4.411	
	14	1.322	2.644	
	Indirect determination (Summation of the extractable and nonextractable radioactivity)			
	3	3.091	4.444	
	14	1.392	2.702	
Metabolites Identified	Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position	[14C-Chloro- phenyl]	[14C-Methoxy- phenyl]	[14C-Chloro- phenyl]	[14C-Methoxy- phenyl]
Lettuce; Day 3	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778	NOA 458422; CGA 380778
Lettuce; Day 14	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778	NOA 458422; CGA 380778

Proposed Metabolic Scheme in Lettuce:

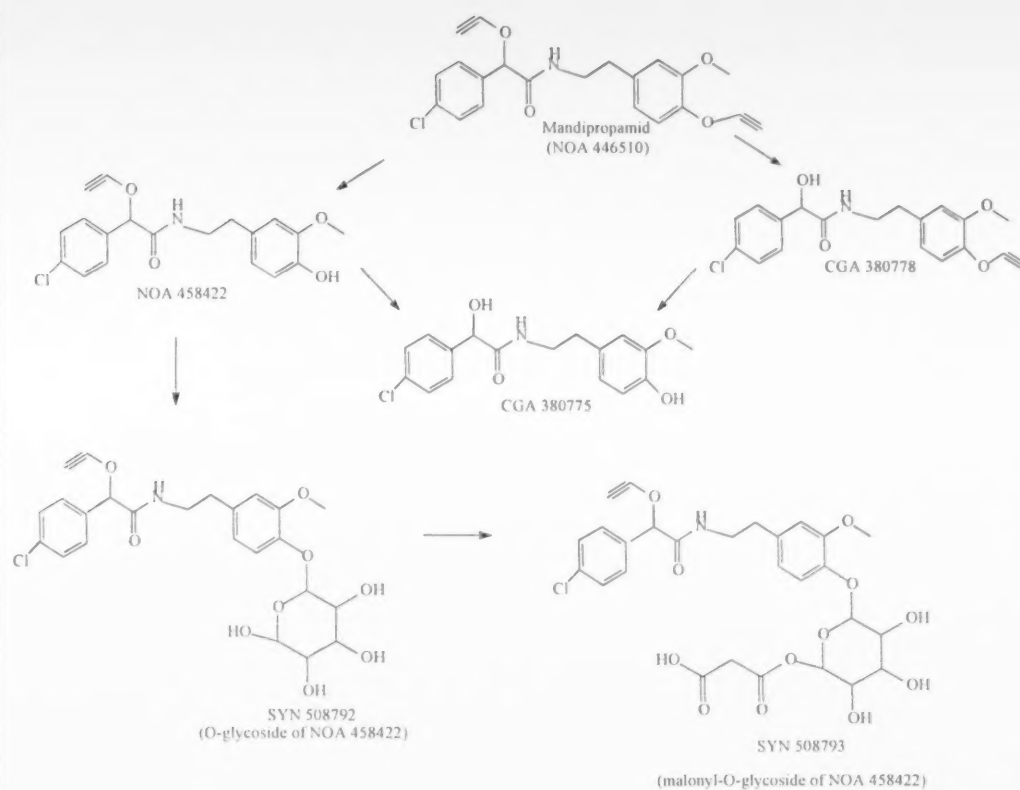
Nature of the Residue in Crop – Potato			PMRA # 1348287
Radiolabel Position	[Chlorophenyl-U-14C]		[Methoxyphenyl-U-14C]
Test site	Field-grown potato plants (1 m ² plots) surrounded by plastic sheeting.		
Treatment	Foliar broadcast applications using a hand-held sprayer. The first application was made to potato plants at the leaf developmental stage (macrostage 1) with the subsequent 5 applications made at 10–12 day re-treatment intervals.		
Rate	Applications 1–3 were made at 146 g a.i./ha. Applications 4–6 were made at 158 g a.i./ha. The total applied rate was 912 g a.i./ha. Exaggerated Treatment Rate: Applications 1–3 were made at 418 g a.i./ha. Applications 4–6 were made at 458 g a.i./ha. The total applied rate was 2.6 kg a.i./ha.	Applications 1–3 were made at 146 g a.i./ha. Applications 4–6 were made at 151 g a.i./ha. The total applied rate was 891 g a.i./ha. Exaggerated Treatment Rate: Applications 1–3 were made at 427 g a.i./ha. Applications 4–6 were made at 452 g a.i./ha. The total applied rate was 2.6 kg a.i./ha.	
End-use product	Suspension concentrate (SC 250).		
Preharvest interval	7 and 21 days for the 1× treatment rate; 21 days for the exaggerated treatment rate.		
Matrix	Radiolabel Position	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]
	PHI (days)	TRR (ppm)	TRR (ppm)
Potato leaves	Direct determination by combustion/LSC		
	7	6.310	5.045
	21	4.237	2.738
	21 (exaggerated rate)	13.795	10.760
	Indirect determination (Summation of the extractable and nonextractable radioactivity)		
	7	6.239	4.814
	21	4.160	2.711
	21 (exaggerated rate)	13.444	10.729
	Direct determination by combustion/LSC		
	7	0.043	0.047
Potato peel	21	0.058	0.040
	21 (exaggerated rate)	0.137	0.114
	Indirect determination (Summation of the extractable and nonextractable radioactivity)		
	7	0.044	0.048
	21	0.059	0.040
	21 (exaggerated rate)	0.141	0.111

Potato flesh	Direct determination by combustion/LSC			
	7	0.042	0.056	
	21	0.049	0.045	
	21 (exaggerated rate)	0.115	0.125	
	Indirect determination (Summation of the extractable and nonextractable radioactivity)			
	7	0.042	0.055	
	21	0.049	0.043	
	21 (exaggerated rate)	0.114	0.122	
Metabolites Identified	Major Metabolites (>10% TRRs)		Minor Metabolites (<10% TRRs)	
Radiolabel Position	[14C-Chloro-phenyl]	[14C-Methoxy-phneyl]	[14C-Chloro-phenyl]	[14C-Methoxy-phenyl]
Potato leaves (PHI = 7 Days)	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778; CGA 380775	NOA 458422; CGA 380778; CGA 380775
Potato leaves (PHI = 21 days)	Mandipropamid	Mandipropamid	NOA 458422; CGA 380778; CGA 380775	NOA 458422; CGA 380778; CGA 380775
Potato peel (PHI = 7 days)	SYN 500003; glucose	Glucose	Mandipropamid; SYN 524199; CGA 155705	Mandipropamid
Potato flesh (PHI = 7 days)	SYN 500003; glucose	Glucose	SYN 524199; CGA 155705	—

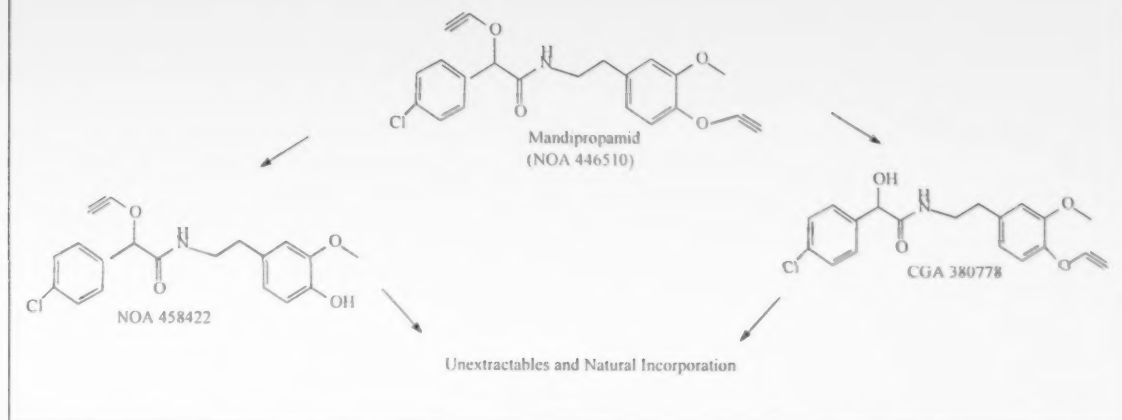
Proposed Metabolic Scheme in Potato:

Nature of the Residue in Crop – Tomato			PMRA #1348285
Radiolabel Position	[1-14C]		
Test site	Residue characterization: field grown tomato plants. Translocation study: tomato plants were grown in plastic pots on the same field plots as for residue characterization. All plants were protected using a transparent plastic roof.		
Treatment	Residue characterization: Mandipropamid (SC 250) was applied to tomato plants as a foliar spray using a hand-held sprayer. The 1st and 2nd applications were made at 2-week intervals and the 3rd and 4th applications were made at weekly intervals. Translocation study: tomato leaves on separate plants were treated once with mandipropamid (SC 250) using a micropipette.		
Rate	Residue characterization: Four sequential applications at 266 g a.i./ha (1st), 295 g a.i./ha (2nd), 147 g a.i./ha (3rd) and 149 g a.i./ha (4th), for a total of 587 g a.i./ha. The 1st application was at the first fruit cluster growth stage. Translocation study: 50 µL of a SC 250 formulation (15 g a.i./hL) per leaf.		
End-use product	Suspension concentrate (SC 250).		
Preharvest interval	Residue characterization: 0, 3, 7, 14 and 28 days after the final 4th application. Translocation study: 0, 3, 7, 14 and 28 days		
	Radiolabel Position	[1-14C]	
Matrix	PHI (days)	TRR (ppm)	TRR (ppm)
Residue characterization			
Tomato leaves	Direct determination by combustion/LSC		
	0	18.221	
	3	18.680	
	7	22.976	
	14	22.234	
	28	9.287	
Mature tomato fruit	Indirect determination (Summation of the radioactivity in the surface wash, extract and post-extractable solids)		
	0	0.945	
	3	0.813	
	7	0.608	
	14	0.465	
	28	0.328	
Immature tomato fruit	28	0.034	

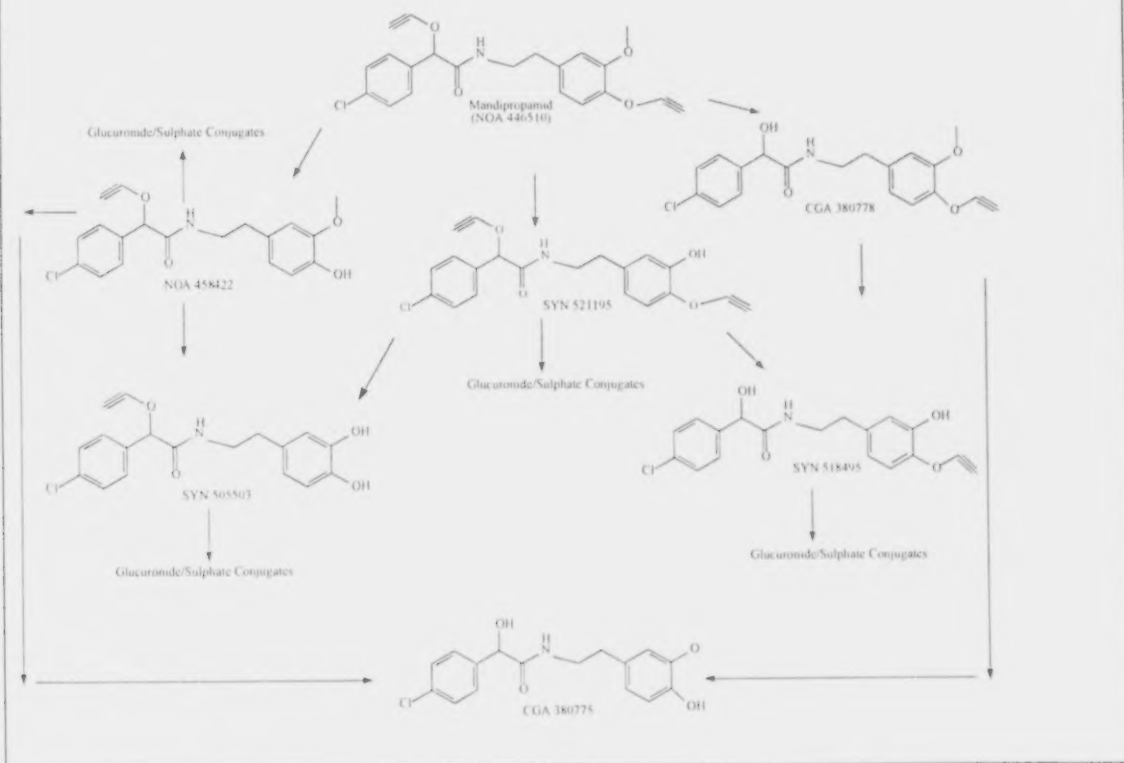
Translocation Study		
	Radiolabel Position	[¹⁻¹⁴ C]
Matrix	PHI (days)	% of the TRRs
Tomato surface wash	0	98.9
	3	94.5
	7	91.5
	14	79.2
	28	60.7
Tomato Leaves	0	1.1
	3	2.3
	7	2.8
	14	7.5
	28	17.0
Metabolites Identified	Major Metabolites (>10% TRRs)	Minor Metabolites (<10% TRRs)
Radiolabel Position	[¹⁻¹⁴ C]	[¹⁻¹⁴ C]
Tomato leaves (0, 3, 7, 14 and 28 days after treatment)	Mandipropamid	NOA 458422; CGA 380778; CGA 380775; SYN 508792; SYN 508793
Mature tomato fruit (0, 3, 7, 14 and 28 days after treatment)	Mandipropamid	NOA 458422; CGA 380778; CGA 380775; SYN 508792; SYN 508793
Immature (Green) tomato fruit (28 days after treatment).	Mandipropamid	NOA 458422; CGA 380778; CGA 380775; SYN 508792; SYN 508793

Proposed Metabolic Scheme in Tomato:

Confined Accumulation in Rotational Crops – Lettuce, Radish, and Spring Wheat				PMRA #1348186, 1348487, 1348188 and 1348189	
Radiolabel Position		[14C-Chloro-phenyl]		[14C-Methoxy-phenyl]	
Test site		The study was conducted on outdoor field plots (6 m ²).The bare soil was treated with mandipropamid (100EC) as a broadcast spray using a small plot sprayer. During treatment the test plot was surrounded with a polythene foil to prevent contamination of the adjacent area.			
Formulation used for trial		Mandipropamid was formulated as an emulsifiable concentrate (EC 100).			
Application rate and timing		Mandipropamid was applied once at 903 g a.i./ha (chlorophenyl label) or at 932 g a.i./ha (methoxyphenyl label) 29 days prior to the first planting of lettuce (seedling), radish (seed) and wheat (seed). Radishes were not grown at the 365 day plant back interval.			
Metabolites Identified		Major Metabolites (>10% TRR)		Minor Metabolites (<10% TRR)	
Matrix	PBI (days)	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]
Lettuce, Head	29	–	Mandipropamid	Mandipropamid	CGA 380778
	58	–	–	Mandipropamid; CGA 380778	Mandipropamid; CGA 380778
	120	–	–	Mandipropamid; CGA 380778	Mandipropamid
Radish, Root	29	Mandipropamid	Mandipropamid	CGA 380778	CGA 380778
	58	Mandipropamid	Mandipropamid	CGA 380778	CGA 380778
Radish, Top	29	–	–	Mandipropamid; CGA 380778	Mandipropamid; CGA 380778
	58	Mandipropamid	Mandipropamid	CGA 380778	CGA 380778
Wheat, Forage	29	–	–	Mandipropamid	Mandipropamid; CGA 380778
	58	Mandipropamid	–	CGA 380778	Mandipropamid; CGA 380778
	120	–	–	Mandipropamid; CGA 380778	Mandipropamid; CGA 380778
Wheat, Grain	29	–	–	Mandipropamid + NOA 458422	–
	58	–	–	–	–
	120	–	–	–	–
Wheat, Straw	29	–	–	Mandipropamid; CGA 380778; NOA 458422	Mandipropamid; CGA 380778; NOA 458422
	58	–	–	Mandipropamid; CGA 380778; NOA 458422	Mandipropamid; CGA 380778; NOA 458422
	120	–	–	Mandipropamid	Mandipropamid
	365	–	–	–	–

Proposed Metabolic Scheme in Rotated Crops

Nature of the Residue in the Lactating Goat		PMRA #1348283, 1410229 and 1410526		
<p>Lactating goats (Alpine breed; n = 2 animals per treatment) were dosed for 7 consecutive days at levels based on the average daily dietary intake of 27–45 ppm (chlorophenyl label) and 30–49 ppm (methoxyphenyl label).</p> <p>The goat dosed at 49 ppm with methoxyphenyl labeled mandipropamid became ill during the dosing period, and samples from this animal were not used.</p> <p>The treated goats were sacrificed 20 h after administration of the final dose. All tissue and milk samples with total radioactive residues (TRRs) >0.01 ppm were extracted and analyzed.</p>				
Matrices	% of the Administered Dose			
	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]		
Urine (cumulative)	31.2	33.0		
Feces (cumulative)	47.4	49.2		
Cage washes (cumulative)	0.28–0.35	0.93		
Milk (cumulative)	0.011	0.048		
Fat (omental and renal)	0.01	0.01		
Muscle (leg and tenderloin)	0.03	0.03		
Liver	0.12	0.09		
Kidney	0.01	0.01		
Bile	0.02	0.05		
Gastrointestinal tract	3.6–9.4	4.1		
Blood (prior to sacrifice)	0.01	0.02		
Metabolites Identified	Major Metabolites (>10% TRR)		Minor Metabolites (<10% TRR)	
Radiolabel Position	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]	[Chlorophenyl-U-14C]	[Methoxyphenyl-U-14C]
Liver	—	—	Mandipropamid; CGA 380775; CGA 380778; SYN 505503; NOA 458422; SYN 521195; SYN 518495	Mandipropamid; CGA 380775; CGA 380778; SYN 505503; NOA 458422; SYN 521195; SYN 518495
Kidney	NOA 458422	NOA 458422	CGA 380775; CGA 380778; SYN 50553; SYN 52119; SYN 518495	CGA 380775; CGA 380778; SYN 50553; SYN 52119; SYN 518495
Fat	Mandipropamid	Mandipropamid	—	—
Milk (Day 4 a.m.)	Not analyzed	—	Not analyzed	Mandipropamid

Proposed Metabolic Scheme in the Lactating Goat:

Storage Stability						PMRA #1348178 and 1410232			
Samples of untreated tomatoes, tomato paste, grapes, grape juice, potato tubers, potato granules/flakes, lettuce, cucumbers, wheat forage, wheat straw, wheat grain, soybeans, soybean meal, soybean hulls, and soybean oil were spiked with mandipropamid at 0.5 ppm and stored frozen at -20°C for up to 24 months.									
Under these conditions, residues of mandipropamid appear to be stable in tomatoes, tomato paste, grapes, grape juice, potato tubers, potato granules/flakes, lettuce, cucumbers, wheat forage, wheat straw, wheat grain, soybeans, soybean meal, soybean hulls, and soybean oil for up to 24 months of frozen storage.									
Crop Field Trials On Brassica Vegetables – Cabbage, Broccoli and Mustard Greens						PMRA #1348183			
During the 2004 growing season, field trials on the representative crops broccoli, cabbage and mustard greens were each conducted at six different locations in the United States to evaluate the magnitude of the residue of mandipropamid in/on brassica vegetables following four postfoliar broadcast applications of a suspension concentrate (250 SC). All applications were made with a non-ionic surfactant (0.25–0.26%; v/v).									
The broccoli field trials were conducted in zones 6 (Texas; 1 trial), 10 (California; 3 trials and Arizona; 1 trial) and 12 (Washington; 1 trial). The cabbage field trials were conducted in zones 1 (New York; 1 trial), 2 (North Carolina; 1 trial), 3 (Florida; 1 trial), 5A (Wisconsin; 1 trial), 6 (Texas; 1 trial) and 10 (California; 1 trial).									
The mustard greens field trials were conducted in zones 2 (Georgia; 1 trial), 4 (Louisiana; 1 trial), 5 (Illinois; 1 trial), 6 (Texas; 1 trial) and 10 (California; 1 trial). Although geographical representation was not met as per DIR98-02 for broccoli (5 trials: 2 trials each in zone 5 and zone 5B; and 1 trial in zone 12), cabbage (5 trials: 2 trials each in zone 5 and zone 5B and 1 trial in zone 12) or mustard greens (5 trials: 2 trials in zone 7 and 3 trials in zone 14), a sufficient number of trials was submitted for each representative crop to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions.									
Therefore, there is a reasonable expectation that the residue profile would be similar in treated Brassica crops from trials conducted in the respective representative Canadian zones. Mature samples of broccoli (flower head and stem), cabbage (heads with and without wrapper leaves, and wrapper leaves alone) and mustard greens (leaves) were harvested one and five to seven days after the last (fourth) application. Residue decline trials were conducted at three trial locations where samples of broccoli, cabbage, or mustard greens were each collected 0, 1, 3, 5, 7, and 9 days after the last application. In the residue decline trials average residues of mandipropamid showed a general decline with increasing sampling intervals.									
The Brassica field trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									
Commodity	Total Application Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Broccoli, flower head and stem	0.603–0.627	0	2	0.118	0.158	0.138	0.138	0.138	N/A
		1	12	0.218	0.699	0.586	0.348	0.389	0.14
		3	2	0.254	0.145	0.296	0.296	0.296	N/A
		5–7	14	<0.01	0.222	0.211	0.382	0.136	0.07
		9	2	0.098	0.147	0.123	0.123	0.123	N/A
Cabbage, heads with wrapper leaves	0.600–0.617	0	2	1.54	2.61	2.08	2.08	2.08	N/A
		1	12	0.406	1.78	1.45	1.1	1.12	0.36
		3	2	0.558	0.926	0.742	0.742	0.742	N/A
		5–7	14	0.086	0.548	0.435	0.221	0.237	0.121
		9	2	0.178	0.295	0.237	0.237	0.237	N/A

Cabbage, heads without wrapper leaves	0.600–0.617	0	2	0.012	0.033	0.022	0.022	0.022	N/A
		1	12	<0.01	0.312	0.252	0.01	0.056	0.096
		3	2	0.027	0.042	0.035	0.035	0.035	N/A
		5–7	14	<0.01	0.013	0.012	0.01	0.01	0.001
		9	2	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Cabbage, wrapper leaves	0.600–0.617	0	2	2.29	4.65	3.47	3.47	3.47	N/A
		1	12	1.86	5.76	4.95	3.23	3.43	1.33
		3	2	1.27	1.63	1.45	1.45	1.45	N/A
		5–7	14	0.315	3.05	2.77	1.21	1.28	0.794
		9	2	0.603	0.644	0.624	0.624	0.624	N/A
Mustard greens, leaves	0.601–0.630	0	2	8.94	10	9.49	9.49	9.49	N/A
		1	10	0.993	11.7	11.49	3.23	4.52	3.84
		3	2	0.761	1.18	0.968	0.968	0.968	N/A
		5–7	12	0.198	5.69	5.57	0.467	1.35	1.99
		9	2	0.116	0.379	0.248	0.248	0.248	N/A
Crop Field Trials On Cucurbits – Cucumber, Cantaloupe and Summer Squash							PMRA #1348182		
During the 2004 growing season, field trials on the representative crops cucumber, cantaloupe and summer squash were each conducted at 4 to 7 different locations in the United States to evaluate the magnitude of the residue of mandipropamid in/on cucurbit vegetables following four postfoliar broadcast applications of a suspension concentrate (250 SC). All applications were made with a non-ionic surfactant (0.25–0.26%; v/v).									
The cucumber field trials were conducted in zones 2 (Georgia and North Carolina; 2 trials), 3 (Florida; 1 trial), 5A (Michigan and Wisconsin; 2 trials), 6 (Texas; 1 trial), and 10 (California; 1 trial). The cantaloupe field trials were conducted in zones 2 (Georgia; 1 trial), 5 (Illinois; 1 trial), 6 (Texas; 1 trial), and 10 (California; 3 trials). The summer squash field trials were conducted in zones 1 (New York; 1 trial), 2 (South Carolina; 1 trial), 3 (Florida; 1 trial), 5 (Illinois; 1 trial), and 10 (California; 1 trial).									
Although geographical representation was not met as per DIR98-02 for cucumber (5 trials: 2 trials each in zone 5 and zone 5B; and 1 trial in zone 12), melons (3 trials: 2 trials in zone 5 and 1 trial in zone 5B) or summer squash (5 trials: 1 trial each in zone 1A and zone 5B; and 2 trials in zone 5), a sufficient number of trials was submitted for each representative crop to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions.									
Therefore, there is a reasonable expectation that the residue profile would be similar in treated cucurbit crops from trials conducted in the respective representative Canadian zones. Mature samples of cucumber, cantaloupe, and summer squash were harvested 0 and 5–7 days after the last (fourth) application (DALA). At three CA trial locations, samples of cucumber, cantaloupe, or summer squash were collected at additional sampling intervals (0, 3, 5, 7, and 9 DALA) to evaluate residue decline. In the residue decline trials, residues of mandipropamid showed a general decline with increasing sampling intervals.									
The cucurbit field trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Cucumber	0.601–0.610	0	14	<0.01	0.071	0.069	0.017	0.028	0.022
		3	2	0.025	0.032	0.028	0.028	0.028	N/A
		5–7	16	<0.01	0.026	0.022	0.01	0.012	0.004
		9	2	0.011	0.011	0.011	0.011	0.011	N/A
Cantaloupe	0.594–0.605	0	12	0.018	0.262	0.232	0.1	0.117	0.074
		3	2	0.031	0.095	0.063	0.063	0.063	N/A
		5–7	14	0.015	0.075	0.073	0.05	0.047	0.02
		9	2	0.031	0.04	0.036	0.036	0.036	N/A
Summer Squash	0.599–0.617	0	10	<0.01	0.079	0.07	0.034	0.039	0.024
		3	2	<0.01	0.017	0.014	0.014	0.014	N/A
		5–7	12	<0.01	0.013	0.011	0.01	0.01	0.001
		9	2	<0.01	<0.01	<0.01	<0.01	<0.01	N/A
Crop Field Trials On Bulb Vegetables – Dry Bulb and Green Onion							PMRA #1348180		
<p>The representative crops for bulb vegetables are dry bulb onions and green onions. During the 2004 growing season, field trials on dry bulb onions were conducted at 8 different locations in the United States to evaluate the magnitude of the residue of mandipropamid in/on dry bulb onions following four postfoliar broadcast applications. Also during the 2004 growing season, field trials on green onions were conducted at three different locations in the United States to evaluate the magnitude of the residue of mandipropamid in/on green onions following three postfoliar broadcast applications. All applications were made with a non-ionic surfactant (0.24–0.27%; v/v). The dry bulb onion field trials were conducted in zones 1 (New York; 1 trial), 5 (Illinois; 1 trial), 6 (Texas; 1 trial), 8 (Colorado; 1 trial), 10 (California; 2 trials), 11 (Idaho; 1 trial) and 12 (Washington 1 trial). The green onion field trials were conducted in zones 2 (Georgia; 1 trial), 6 (Texas; 1 trial) and 10 (California; 1 trial).</p> <p>Although geographical representation was not met as per DIR98-02 each for dry onions (5 trials: 3 trials in zone 5 and 2 trials in zone 5B) or green onions (2 trials: 1 trial each in zone 5 and zone 5B), a sufficient number of trials was submitted for the representative crops to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions. Therefore, there is a reasonable expectation that the residue profile would be similar in treated bulb vegetables from trials conducted in the respective representative Canadian zones.</p> <p>Mature samples of dry onion bulbs were harvested 5–10 and 14–15 days after the last (fourth) treatment. Mature samples of green onions were harvested 7 days after the last (third) application. Residue decline trials were conducted at two trial locations where samples of dry bulb onions were collected 0, 3, 5, 7, 9, 14 and 15 days after the last application and samples of green onions were collected at 0, 3, 5, 7 and 9 days after the last application. In the green onion residue decline trial, residues of mandipropamid showed a general decline with increasing sampling intervals. In the dry bulb onion decline trial, residues of mandipropamid declined rapidly to below the method LOQ (<0.01 ppm) by Day 5.</p>									
<p>The dry bulb and green onion trials were conducted with a 250 SC formulation (250 g mandipropamid/L).</p> <p>The LOQ for mandipropamid was reported as 0.01 ppm.</p>									

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Onion, Green	0.450– 0.455	0	2	1.22	1.5	1.36	1.36	1.36	N/A
		3	2	0.566	0.728	0.647	0.647	0.647	N/A
		5–9	10	0.099	1.74	1.44	0.329	0.537	0.518
Onion, Dry Bulb	0.596– 0.650	0	2	<0.01	0.018	0.014	0.014	0.014	N/A
		3	2	0.026	0.033	0.03	0.03	0.03	N/A
		5–10	20	<0.01	0.04	0.029	0.01	0.012	0.007
		14–15	18	<0.01	<0.01	<0.01	<0.01	<0.01	0
Crop Field Trials On Fruiting Vegetables – Bell Peppers, Non-Bell Peppers (Hot Peppers) and Tomatoes							PMRA #1348185		

During the 2003 and 2004 growing seasons, field trials on the representative crops bell peppers, non-Bell peppers (hot) and tomatoes were each conducted at 3–9 different locations in the United States (NAFTA representative zones) to evaluate the magnitude of the residue of mandipropamid in/on fruiting vegetables following four postfoliar broadcast applications of a suspension concentrate (250 SC). All applications were made with a non-ionic surfactant (0.24–0.26%; v/v). The Bell pepper field trials were conducted in zones 2 (North Carolina; 1 trial), 3 (Florida; 1 trial), Illinois; 1 trial), 5 (Illinois; 1 trial), 6 (Texas; 1 trial) and 10 (California; 2 trials). The non-Bell pepper field trials were conducted in zones 6 (Texas; 1 trial), 8 (New Mexico; 1 trial) and 10 (California; 1 trial).

The tomato field trials were conducted in zones 1 (New York; 1 trial), 2 (South Carolina; 1 trial), 3 (Florida; 2 trials), 5 (Illinois; 1 trial) and 10 (California; 6 trials). Although geographical representation was not met as per DIR98-02 for tomatoes (12 trials: 11 trials in zone 5 and 1 trial in zone 5B) or peppers (5 trials: 4 trials in zone 5 and 1 trial in zone 5B), a sufficient number of trials was submitted for each crop to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions. Therefore, there is a reasonable expectation that the residue profile would be similar in treated peppers and tomatoes from trials conducted in the respective representative Canadian zones.

Mature samples of peppers (Bell and non-Bell) and tomatoes were harvested 1 and 3 days after the last (fourth) application. In one Bell pepper trial and two tomato trials, samples were collected at additional sampling intervals (0, 1, 2, 3 and 4 DALA) to evaluate residue decline. Residues of mandipropamid showed a general decline with increasing sampling intervals.

The fruiting vegetables field trials were conducted with a 250 SC formulation (250 g mandipropamid/L).

The LOQ for mandipropamid was reported as 0.01 ppm.

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Bell peppers	0.574– 0.608	0	2	0.05	0.116	0.083	0.083	0.083	N/A
		1–2	14	0.027	0.338	0.327	0.068	0.104	0.101
		3–4	14	0.026	0.286	0.275	0.06	0.088	0.082
Non-Bell peppers (hot)	0.602– 0.609	1	6	0.055	0.375	0.37	0.166	0.206	0.138
		3	6	0.048	0.257	0.238	0.112	0.137	0.085
Tomatoes	0.594– 0.628	0	4	0.025	0.104	0.102	0.063	0.064	0.044
		1–2	26	0.015	0.199	0.181	0.063	0.064	0.044
		3–4	26	<0.010	0.097	0.082	0.028	0.036	0.024

Crop Field Trials On Grapes						PMRA #1348179			
During the 2003 growing season, field trials on grapes were each conducted at 12 different locations in the United States to evaluate the magnitude of the residue of mandipropamid in/on grapes following four postfoliar broadcast applications of a suspension concentrate (250 SC). The grape field trials were conducted in zones 1 (New York and Pennsylvania; 2 trials), 10 (California; 8 trials), 11 (Washington; 1 trial), and 12 (Oregon; 1 trial).									
Although geographical representation was not met as per DIR98-02 for grapes (5 trials: 4 trials in zone 5 and 1 trial in zone 11), a sufficient number of grape trials was submitted to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions. Therefore, there is a reasonable expectation that the residue profile would be similar in treated grapes from trials conducted in the respective representative Canadian zones.									
Samples of mature grapes were harvested 14–15 and 27–28 days after the last application from all treatment plots. At two California trial locations, grapes were collected at additional sampling intervals to evaluate residue decline. Grapes were harvested at 0, 5, 10, 14, 20, and 28 days or at 8, 14, 21, 28, and 35 days after the last application. Residues of mandipropamid generally decreased with increasing sampling intervals.									
The grape field trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									
Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Grape	0.596–0.624	0	2	0.319	0.337	0.328	0.328	0.328	N/A
		5–10	6	0.163	1.43	1	0.491	0.571	0.448
		14–15	24	0.066	0.822	0.668	0.31	0.369	0.219
		20–21	4	0.078	0.509	0.426	0.249	0.271	0.194
		27–28	24	0.094	0.684	0.625	0.261	0.32	0.196
		35	2	0.079	0.087	0.083	0.083	0.083	N/A
Crop Field Trials On leafy Vegetables – Leaf Lettuce, Head Lettuce, Celery and Spinach						PMRA #1410233			
During the 2005 growing season, field trials on the representative crops lettuce, celery and spinach were each conducted at 16 different locations in the United States (NAFTA representative zones) to evaluate the magnitude of the residue of mandipropamid in/on leafy vegetables following four postfoliar broadcast applications of a suspension concentrate (250 SC). All applications were made with a non-ionic surfactant (0.24–0.26% v/v). The leaf lettuce field trials were conducted in zones 1 (New York; 1 trial), 3 (Florida; 1 trial) and 10 (Arizona and California; 4 trials). The head lettuce field trials were conducted in zones 1 (New York; 1 trial) and 10 (Arizona and California; 4 trials). The celery field trials were conducted in zones 3 (Florida; 1 trial), 5A (Michigan; 1 trial) and 10 (California; 4 trials). The spinach field trials were conducted in zones 1 (New York; 1 trial), 2 (New Jersey; 1 trial), 6 (Texas; 1 trial), 9 (Colorado; 1 trial) and 10 (California; 2 trials).									
Although geographical representation was not met as per DIR98-02 for lettuce (5 trials: 1 trial each in zone 5 and zone 12; and 3 trials in zone 5B) and spinach (3 trials: 1 trial each in zone 5, zone 5B and zone 12), a sufficient number of trials was submitted for each crop to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions. Therefore, there is reasonable expectation the residue profile would be similar in treated lettuce and spinach from trials conducted in the respective representative Canadian zones.									
Mature samples of leaf lettuce, head lettuce (with wrapper leaves, without wrapper leaves and wrapper leaves only), celery (leaf stalks) and spinach (leaves) were harvested 1 and 7–9 days after the last (fourth) application. One decline trial was conducted for each representative commodity: leaf lettuce, head lettuce, celery, and spinach. The residue decline data demonstrated a general decline for all crops with increasing time after application.									
The leafy vegetable field trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Lettuce, leaf	0.595– 0.625	0	2	10	13.5	11.8	11.8	11.8	N/A
		1	12	1.07	7.91	7.87	5.18	5	2.18
		3	2	6.48	6.79	6.64	6.64	6.64	N/A
		7–9	14	0.18	4.21	3.65	1.49	1.78	1.2
Lettuce, head with wrapper leaves	0.597– 0.621	0	2	1.47	2.12	1.8	1.8	1.8	N/A
		1	10	0.98	9.56	8.29	2.66	3.85	2.75
		3–5	4	0.965	4.23	2.99	2.83	2.71	1.61
		7–9	12	0.374	3.51	2.59	0.758	1.19	0.905
Lettuce, head without wrapper leaves	0.597– 0.621	0	2	0.043	0.053	0.048	0.048	0.048	N/A
		1	10	0.022	1.15	0.952	0.077	0.256	0.381
		3–5	4	<0.01	0.039	0.03	0.018	0.012	0.013
		7–9	12	<0.01	0.087	0.054	0.01	0.02	0.022
Lettuce, head wrapper	0.597– 0.621	0	2	9.8	12	10.9	10.9	10.9	N/A
		1	10	3.28	12	11.6	7.62	7.95	2.5
		3–5	4	7.31	10.6	8.75	9	8.97	1.65
		7–9	12	0.871	10.4	8.77	5.3	5.04	2.71
Celery, leaf stalks	0.598– 0.618	0	2	3.16	7.41	5.29	5.29	5.29	N/A
		1	12	0.384	6.44	5.7	2.59	2.98	2.15
		3–5	4	1.26	2.95	2.28	2.28	2.19	0.844
		7–9	14	0.536	1.85	1.73	0.94	1.12	0.419
Spinach leaves	0.605– 0.625	0	2	11.9	12.3	12.1	12.1	12.1	N/A
		1	12	5.11	11	10.7	9.33	8.86	1.95
		3–5	4	4.51	4.88	4.74	4.74	4.72	0.169
		7–9	14	1.28	4.16	4.11	2.54	2.44	0.967

Crop Field Trials On Potato						PMRA #1348181 and 1457579			
During the 2003–2004 growing season, field trials on potatoes were conducted at 15 different locations in the United States (NAFTA representative zones) to evaluate the magnitude of the residue of mandipropamid in/on potatoes following four postfoliar broadcast applications of a suspension concentrate (250 SC). The potato field trials were conducted in zones 1 (Maine and New York; 2 trials), 2 (North Carolina; 1 trial), 3 (Florida; 1 trial), 5 (Minnesota, North Dakota; 2 trials); 5A (Michigan and Wisconsin; 2 trials), 9 (Colorado; 1 trial), 10 (California; 1 trial), and 11 (Idaho, Oregon, and Washington; 6 trials).									
Although geographical representation was not met as per DIR98-02 for potatoes (16 trials: 3 trials in zone 1; 4 trials in zone 1A; 3 trials in zone 5; 1 trial each in zone 5A, zone 5B, zone 7A and zone 12; and 2 trials in zone 14), a sufficient number of potato trials was submitted to demonstrate that residues of mandipropamid were fairly consistent across different geographical zones, each with different soil and climatic conditions. Therefore, there is a reasonable expectation that the residue profile would be similar in treated grapes from trials conducted in the respective representative Canadian zones.									
Samples of potato tubers were harvested 13–14 and 21–28 days after the last application from all treatment plots. At two trial locations, potato tubers were collected at additional sampling intervals to evaluate residue decline; potatoes were collected 0, 3, 7, 14, 21, 28, and 35 days after the last application. Residue decline data from both potato field trials were inconclusive because residues of mandipropamid were below the LOQ (<0.01 ppm) at all sampling intervals. Residues of the metabolite SYN 500003 in one of the decline trials were also below the LOQ (<0.005 ppm) at all sampling intervals. The results of the other potato field trial, however, showed a decline in SYN 500003 residues with increasing PHIs.									
The potato trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ was reported as 0.01 ppm for mandipropamid and as 0.005 ppm for the metabolite SYN 500003.									
Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Potato Tubers	0.580–0.615	Mandipropamid							
		0	4	<0.01	<0.01	<0.01	<0.01	<0.01	0
		3–7	8	<0.01	<0.01	<0.01	<0.01	<0.01	0
		13–14	32	<0.01	<0.01	<0.01	<0.01	<0.01	0
		21–35	39	<0.01	<0.01	<0.01	<0.01	<0.01	0
		SYN 500003							
		0	4	<0.005	0.016	0.015	0.01	0.01	0.006
		3–7	8	<0.005	0.012	0.011	0.007	0.008	0.003
		13–14	32	<0.005	0.015	0.015	0.006	0.007	0.003
		21–35	12	<0.005	0.01	0.01	0.005	0.006	0.002
European Trials On Greenhouse Cucumber					PMRA# 1410234, 1410235, 1410236, 1410237, 1410238 and 1410239				
During the 2003–2004 growing season, eight residue decline trials on greenhouse cucumbers were conducted at seven different locations in Europe (Switzerland, Spain, France and the Netherlands) to evaluate the magnitude of the residue of mandipropamid in/on greenhouse cucumbers following four postfoliar applications of a suspension concentrate (250 SC). Samples of mature cucumber were harvested 0, 1, 3, 6–8 and 14 days after the final (fourth application). Residues of mandipropamid declined over the 14-day sampling period in cucumber samples harvested from all trial sites.									
The cucumber greenhouse trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Cucumber, fruit	0.572– 0.608	0	8	0.04	0.12	0.12	0.07	0.07	0.03
		1	8	0.02	0.10	0.10	0.08	0.07	0.03
		3	8	0.02	0.09	0.09	0.05	0.05	0.03
		6–8	8	<0.01	0.05	0.05	0.02	0.02	0.02
		14	8	<0.01	0.01	0.01	0.01	0.01	0
European Trials On Greenhouse Head Lettuce						PMRA #1410240, 1410241, 1410242, 1410243 and 1410244			
During the 2003–2004 growing season, residue decline trials on greenhouse lettuce (head variety) were conducted at five different locations in Europe (Switzerland, Spain, France and northern and southern and Italy) to evaluate the magnitude of the residue of mandipropamid in/on greenhouse lettuce following 1–2 postfoliar applications of a suspension concentrate (250 SC). Samples of mature lettuce were harvested 0, 3, 7, 14 and 20–21 days. Residues of mandipropamid in harvested lettuce samples generally declined over the 20- to 21-day sampling period.									
The greenhouse lettuce trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									
Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Lettuce, head	0.146– 0.154	0	5	2.9	4.1	4.1	3.1	3.36	0.52
		3	5	2.2	5.1	5.1	3.5	3.48	1.26
		7	5	0.93	3.3	3.3	2.5	2.27	0.92
		14	5	0.37	3.2	3.2	2.1	1.90	1.27
		20–21	5	0.05	2.8	2.8	2	1.53	1.16
Lettuce, head	0.292– 0.309	0	9	3.4	7.9	7.9	5.7	6	1.48
		3	9	3.5	8.7	8.7	6.2	5.93	1.82
		7	9	1.6	7.1	7.1	4.9	4.53	2.04
		14	9	0.36	5.7	5.7	4.1	3.27	2.04
		20–21	9	0.05	4.9	4.9	3.4	2.70	1.9
European Trials On Greenhouse Tomato							PMRA #1348172		
During the 2003–2004 growing season, residue decline trials were conducted in Europe on greenhouse tomatoes (2 trials in France, 2 trials in Switzerland, 1 trial in Germany, 3 trials in Spain and 1 trial in Italy) and cherry tomatoes (2 trials in Spain and 3 trials in Italy) to evaluate the magnitude of the residue of mandipropamid in/on greenhouse tomatoes and cherry tomatoes following 4 postfoliar applications of a suspension concentrate (250 SC). Samples of mature tomato and cherry tomato fruit were harvested 0, 1, 3, 6–7, and 14–15 days after the final (fourth application). Residues of mandipropamid decreased in the fruit from some of the tomato trials and for the majority of the cherry tomato trials over the 14–15 day sampling interval.									
The greenhouse tomato and cherry tomato trials were conducted with a 250 SC formulation (250 g mandipropamid/L).									
The LOQ for mandipropamid was reported as 0.01 ppm.									

Commodity	Total Applic. Rate (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Tomato, Fruit	0.563–0.618	0	13	0.04	0.59	0.59	0.14	0.2	0.17
		1	13	0.04	0.45	0.45	0.16	0.20	0.13
		3	13	0.04	0.4	0.4	0.14	0.17	0.11
		7	13	0.03	0.38	0.38	0.13	0.17	0.11
		14	13	0.03	0.27	0.27	0.14	0.15	0.08
Cherry Tomato, Fruit	0.597–0.606	0	5	0.3	0.59	0.59	0.37	0.42	0.14
		1	5	0.27	0.65	0.65	0.29	0.4	0.17
		3	5	0.28	0.6	0.6	0.33	0.40	0.15
		6–7	5	0.3	0.48	0.48	0.34	0.37	0.08
		14–15	5	0.23	0.37	0.37	0.29	0.29	0.05

Field Accumulation In Rotational Crops – Radish, Spinach and Wheat**PMRA #1348190**

Three field trials were conducted in the United States (1 trial in New York, zone 1 and 2 trials in Illinois, zone 5), during the 2004 growing season. Mandipropamid (250 SC formulation) was applied four times as a postfoliar broadcast application at 6 to 8-day re-treatment intervals to the primary crop cucumber at 147–155 g a.i./ha/application for a total seasonal rate of 597–607 g a.i./ha. Applications were made using ground equipment in 180–236 L/ha with a non-ionic surfactant (0.25%; v/v). Rotational crops (radish, spinach, and wheat) were planted 28–31 or 60 days after the last application and removal of the primary crop cucumber.

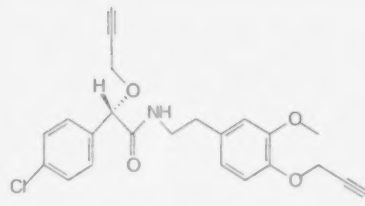
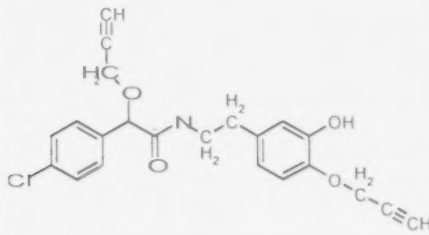
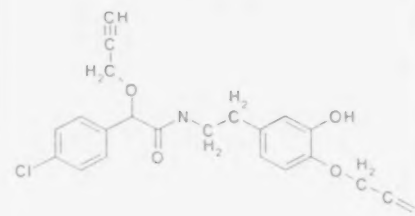
Commodity	Total Applic. Rate (kg a.i./ha)	PBI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Standard Deviation
Spinach, leaves	0.597– 0.607	28–31	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Radish, tops		28–31	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Radish, roots		28–31	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Wheat,fall forage		28–31	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Wheat, spring forage		28–31	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Wheat, hay		28–31	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Wheat, grain		28–31	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Wheat, straw		28–31	4	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
		61	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

Processed Food and Feed – Grapes		PMRA #1348179
Test site	Zone 10 (California)	
Treatment	Four postfoliar broadcast applications	
Rate	Total of 0.61–0.62 kg a.i./ha or 3.0–3.1 kg a.i./ha	
End-use product	250 SC (250 g a.i. mandipropamid/L)	
Preharvest interval	14 or 28 days	
Processed commodity	Processing factor	
Grape, raisin	2.1–7.6	
Grape, juice	<1	
Grape, wine	0.97–2.8	
Processed Food and Feed – Potato		PMRA #1348181 and 1457579
Test site	Zone 11 (Idaho)	
Treatment	Four postfoliar broadcast applications	
Rate	Total of 0.61 kg a.i./ha or 3.1 kg a.i./ha	
End-use product	250 SC formulation (250 g a.i./L mandipropamid)	
Preharvest interval	14 days	
Following treatments at the seasonal rate of 0.61 kg a.i./ha, residues of mandipropamid were below the LOQ (<0.01 ppm) in both the raw agricultural commodity (RAC) and all processed fractions; therefore, processing factors could not be calculated. Following treatments at the seasonal rate of 3.1 kg a.i./ha, residues of mandipropamid were also below the LOQ (<0.01 ppm) in the RAC and all processed fractions except in potato wet peel, for which a quantifiable residue level (0.03 ppm) was detected.		
When adjusted for the degree of exaggeration (~5x) as per DIR98-02 (Section 10.6.3 Use of Exaggerated Rate Studies), residues of mandipropamid in wet peel were <LOQ (0.006 ppm). Therefore, a processing factor could not be calculated. Processing factors for the metabolite SYN 500003 could not be calculated because residues were below the LOQ (<0.005 ppm) in both the RAC and processed fractions.		
Processed Food and Feed – Tomato		PMRA #1348185
Test site	Zone 10 (California)	
Treatment	Four postfoliar broadcast applications	
Rate	Total of 0.60–0.61 kg a.i./ha or 3.0 kg a.i./ha	
End-use product	250 SC formulation (250 g a.i./L mandipropamid)	
Preharvest interval	1 or 3 days	
Processed commodity	Processing factor	
Tomato paste	2.5–7.1	
Tomato purée	0.8–2.3	
Livestock Feeding – Dairy Cattle and Laying Hens		
Finite residues of mandipropamid are not anticipated in the milk, meat and eggs from the proposed uses.		

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

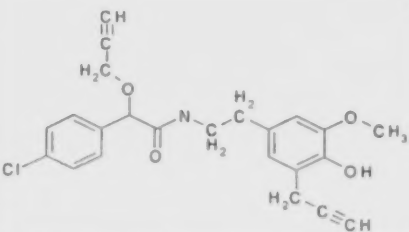
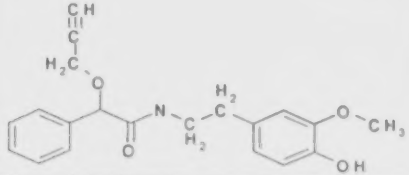
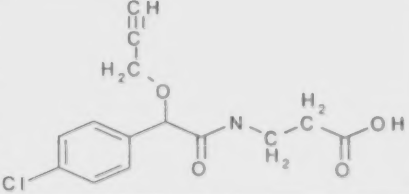
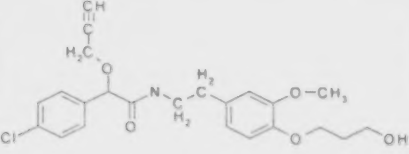
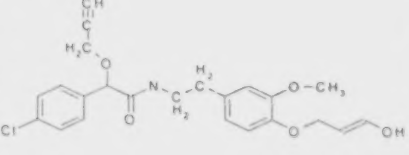
Plant Studies			
Residue definition for enforcement			
Primary crops		Mandipropamid	
Rotational crops		Mandipropamid	
Residue definition for enforcement		Mandipropamid in all crops except root and tuber vegetables; mandipropamid and the metabolite SYN 500003 in Root and Tuber Vegetables	
Primary crops			
Rotational crops		Mandipropamid	
Metabolic profile in diverse crops		Unchanged mandipropamid was the principal residue component identified in all analyzed crop matrices. Mandipropamid undergoes extensive metabolism to form a range of metabolites that are structurally related to or more polar than the parent compound mandipropamid.	
Animal Studies			
Animals		Ruminant	
Residue definition for enforcement		Mandipropamid	
Residue definition for risk assessment		Mandipropamid	
Metabolic profile in animals (goat and rat)		The metabolic profile was similar in the goat and rat.	
Fat soluble residue		Yes (K _{ow} = 3.2 at pH 7.5–7.7, 25°C)	
Dietary Risk From Food and Water			
Refined chronic non-cancer dietary risk ADI = 0.05 mg/kg bw Estimated chronic drinking water concentration = 5.9 µg/L for total residues of mandipropamid and the transformation products SYN 500003 and SYN 504851	Population	Estimated Risk – % of Acceptable Daily Intake (ADI)	
		Food Only	Food and Water
	All infants <1 year	3.4	4.2
	Children 1–2 years	5.0	5.3
	Children 3–5 years	4.3	4.7
	Children 6–12 years	3.1	3.3
	Youth 13–19 years	2.5	2.6
	Adults 20–49 years	3.3	3.6
	Adults 50+ years	3.7	3.9
	Females 13–49 years	3.4	3.7
	Total population	3.4	3.6

Table 7 Major and Minor Transformation Products

Chemical Name	Code	Chemical Structure	Occurrence (Max Amounts on Individual Replicates)	
			System	% AR
Major Transformation Products				
2-(4-Chlorophenyl)-N-[2-(3-methoxy-4-prop-2-ynyloxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide	SYN 504213 (S-isomer of mandipropamid)		S-isomer of mandipropamid	
2-(4-Chlorophenyl)-N-[2-(3-hydroxy-4-prop-2-ynyloxy-phenyl)ethyl]-2-prop-2-ynyloxy-acetamide	SYN521195		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic – water/sed. – system: – sed: – water: Outdoor pond: Anaerobic – water/sed – system: – sed: – water:	0 0 0 0 17.7 15.6 3.4 10.8 15.4 12.5 3.9
N-[2-(4-Allyloxy-3-hydroxy-phenyl)-ethyl]-2-(4-chlorophenyl)-2-prop-2-ynyloxy-acetamide	SYN539678		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed. system: – sed: Outdoor pond: Anaerobic – water/sed – system: – sed: – water:	0 0 0 0 12.6 11.2 6.9 24.2 17.5 6.7

Chemical Name	Code	Chemical Structure	Occurrence (Max Amounts on Individual Replicates)	
			System	% AR
Allyloxy-(4-chloro-phenyl)-acetic acid.	SYN504851		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed. system: - sed: - water: Outdoor pond: Anaerobic - water/sed - system: - sed: - water:	0 0 0 0 38.5 28.5 10.0 11.1 72.1 44 26.5
4-Chloro-alpha-(2-propynyloxy)-benzeneacetic acid.	SYN500003		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond: Anaerobic - water/sed - system: - sed: - water:	0.3 0 0 3.7 ^c 9.4 6.4 26.1 14.3 15.9
Minor Transformation Products				
2-(4-Chlorophenyl)-N-[2-(4-hydroxy-3-methoxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide.	NOA458422		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	1.7 1.0 1.7 4.5 0 0
4-Chloro-alpha-hydroxy-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]benzeneacetamide	CGA380778		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0.6 0.5 9.4/6.2 ^b 0 0 0
4-Chloro-alpha-hydroxy-benzeneacetic acid	NOA495119		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0.2 0 0 0 0 0

Chemical Name	Code	Chemical Structure	Occurrence (Max Amounts on Individual Replicates)	
			System	% AR
2-(4-Chlorophenyl)-N-[2-(3,4-dihydroxyphenyl)-ethyl]-2-prop-2-ynyloxy-acetamid.	SYN505503		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	T 0 3.0 0 0 0
4-Chloro- α -hydroxy-N-[2-(4-hydroxy-3-methoxyphenyl)ethyl]benzeneacetamide.	CGA380775		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0.6 0.5 9.4/6.2 ^b 0 0 0
N-[2-(Allyloxy-3-methoxyphenyl)-ethyl]-2-(4-chlorophenyl)-2-prop-2-ynyloxy-acetamide.	SYN536638		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond: Anaerobic - water/sed - system: - sed: - water:	3.0 <LOD 0 0 8.4 ^a 1.9 7.9 ^a 6.8 ^a 1.3 ^a
2-Allyloxy-N-[2-(4-allyloxy-3-hydroxyphenyl)-ethyl]-2-(4-chlorophenyl)-acetamide	SYN539679		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond: Anaerobic - water/sed - system: - sed: - water:	0 0 0 0 8.4 ^a 1.0 7.9 ^a 6.8 ^a 1.3 ^a
N-[2-(3,4-dioxocyclohex-1-enyl)-ethyl]-2-(4-hydroxyphenyl)-2-prop-2-ynyloxy-acetamide.	U9		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0 0 0 3.4 0 0

Chemical Name	Code	Chemical Structure	Occurrence (Max Amounts on Individual Replicates)	
			System	% AR
2-(4-Chlorophenyl)-N-[2-(4-hydroxy-3-methoxy-5-prop-2-ynyl-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide.	U39		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0 0 0 4.7 0 0
N-[2-(4-hydroxy-3-methoxy-phenyl)-ethyl]-2-phenyl-2-prop-2-ynyloxy-acetamide.	U29a		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0 0 0 3.7 ^c 0 0
3-[2-(Chlorophenyl)-2-prop-2-ynyloxy-acetylmino]-propionic acid.	SYN524197 U24d		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	0 0 3.6 0 0 0
2-(4-Chlorophenyl)-N-{2-(4-(3-hydroxypropoxy)-3-methoxyphenyl)ethyl}-2-prop-2-ynyloxy acetamide	U7		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	1.1 0 0 0 0 0
2-(4-Chlorophenyl)-N-{2-[4-((E)-3-hydroxyallyloxy)-3-methoxyphenyl]ethyl}-2-prop-2-ynyloxy acetamide	U8		Lab. soil: Field soil: Soil photolysis: Photolysis water: Aerobic water/sed.: Outdoor pond:	1.2 0 0 0 0 0

^a SYN 536638 and SYN 539679 could not be adequately separated in laboratory water/sediment studies (sum of both stated).

^b 9.4% of AR based on HPLC (together with an unknown substance), 6.2% of AR based on TLC.

^c SYN 500003 and U29a co-eluting (sum of both stated).

T = traces.

Table 8 Fate and Behaviour of Mandipropamid in the Terrestrial Environment

Property	Test substance	Value	Comments	Reference (PMRA #)
Abiotic Transformation				
Hydrolysis	Mandipropamid	Stable	Will not contribute to the dissipation of mandipropamid in the terrestrial environment	1348292
Phototransformation on soil	Mandipropamid	$T_{1/2} = 32.5\text{--}46.4$ d	Environmental half-lives for 40°N Phototransformation on soil is not likely to contribute significantly to the dissipation of mandipropamid in the environment	1348294 1348296
Phototransformation in air	Mandipropamid	Not required		—
Biotransformation				
Biotransformation in aerobic soil	Mandipropamid	<u>Simple First order kinetics</u> $DT_{50} = 14\text{--}86$ d $DT_{90} = 65\text{--}284$ d <u>1st-order $t_{1/2}$</u> 80 th percentile $DT_{50} = 80.6$ d	Slightly to moderately persistent ^a	1348312 1348305 1348309 1348330 1348307
	CGA380778	<u>Simple first order kinetics</u> $DT_{50} = 3\text{--}72$ d $DT_{90} = 10\text{--}138$ d	Non- to slightly persistent ^a	1348308
	SYN504851 ^c	<u>Simple first order kinetics</u> $DT_{50} = 1.2\text{--}5.7$ d $DT_{90} = 3.9\text{--}18.9$ d	Non-persistent ^a	1348326
	SYN536638 ^c	<u>Simple first order kinetics</u> $DT_{50} = 15.7\text{--}32.5$ d $DT_{90} = 52.3\text{--}108$ d	Slightly persistent ^a	1348326
	SYN500003 ^c	<u>Simple first order kinetics</u> $DT_{50} = 1.2\text{--}4.0$ d $DT_{90} = 3.9\text{--}13.2$ d	Non-persistent ^a	1348326
	SYN521195 ^c	<u>Simple first order kinetics</u> $DT_{50} = 0.26\text{--}0.34$ d $DT_{90} = 0.87\text{--}1.13$ d	Non-persistent ^a	1348326

Biotrans- formation in anaerobic soil	Mandipropamid	<u>Simple first order kinetics</u>	Moderately persistent to persistent ^a	1348307 1348312
		DT ₅₀ = 1f1, 187 d DT ₉₀ = 501, 622 d		
Mobility				
Adsorption/ desorption in soil	Mandipropamid	K _{FOC} = 411–1228 20 th percentile = 648.8	Moderate to low mobility ^b	1348341 1348343
	CGA380778	K _{FOC} = 360–501 20 th percentile = 407.2		
	SYN521195	K _{FOC} = 568–1552 20 th percentile = 798.4	Low mobility ^b	1348337
	SYN539678	K _{FOC} = 430–2100 20 th percentile = 1058	Moderate to slight mobility ^b	1348339
	SYN500003	K _{FOC} = 3–29 20 th percentile = 11.7	Very high mobility ^b	1348340
	SYN504851	K _{FOC} = 3–8 20 th percentile = 3.8	Very high mobility ^b	1348347
Volatilization		vp <7.05 × 10 ⁻⁹ mm Hg	Not volatile	—
		HLC <9.1 × 10 ⁻¹⁰ atm m ³ /mole	Not volatile from water and moist surfaces	
Field studies				
Field dissipation (New York)	Mandipropamid	27.5 d (bare plot) 102.8 d (cropped plot)	Mandipropamid is classified as slightly persistent on a bare plot and moderately persistent on a cropped plot. ^a	1348192

^a Classified according to the classification of Goring, C. A. I., Laskowski D. A., Hamaker, J. W., and Meikle R. W., 1975. Principles of Pesticide Degradation in Soil. In: *Environmental Dynamics of Pesticides*. Haque, R., and Freed, V. H. (Eds). Plenum Press, New York, pp. 135–172.

^b Classified according to the classification of McCall, J.P., D.A. Laskowski, R.L. Swann and J.J. Dishburger. (1981). Measurement of sorption coefficients of organic chemicals and their use in environmental fate analysis. In *Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium*. Association of Official Analytical Chemists. 94th Annual Meeting, October 21–22, 1980, Washington, DC, pp. 89–109.

^c Data not submitted to the PMRA, reviewed by the OECD-RMS, details available in PMRA 1348326

Table 9 Fate and Behaviour in the Aquatic Environment

Property	Test material	Value	Comments	Reference (PMRA#)
Abiotic transformation				
Hydrolysis	Mandipropamid	Stable		1348292
Phototransformation in water	Mandipropamid	$T_{1/2} = 1.5\text{--}1.7$ d at 40°C	Phototransformation in the aquatic environment will contribute significantly to the dissipation of mandipropamid in the environment.	1348299 1348300 1348303 1348301
Biotransformation				
Biotransformation in aerobic water systems	Mandipropamid	<p><u>Water: Simple 1st order & 1st order multi-compartment kinetics</u></p> <p>$DT_{50} = 0.19\text{--}14.5$ d</p> <p>$DT_{90} = 7.1\text{--}45.4$ d</p> <p><u>Water: Estimated 1st order $t_{1/2}$</u></p> <p>80th percentile = 9.1 d</p> <p><u>Sediment: 1st-order multi-compartment kinetics sediment</u></p> <p>$DT_{50} = 5.3\text{--}20.6$ d</p> <p>$DT_{90} = 50.9\text{--}65.4$ d</p> <p><u>Sediment: Estimated 1st order $t_{1/2}$</u></p> <p>80th percentile = 18.6 d</p> <p><u>System: Simple 1st-order & 1st-order multi-compartment kinetics</u></p> <p>$DT_{50} = 7.8\text{--}25.8$ d</p> <p>$DT_{90} = 31.1\text{--}77.8$ d</p> <p><u>System: Estimated 1st order $t_{1/2}$</u></p> <p>80th percentile = 21.7 d</p>	Mandipropamid is classified as non-persistent to slightly persistent in the total system under aerobic conditions in the aquatic environment.*	1348333 1348335

Dissipation in aerobic water/sediment system (calculated from the data obtained on the formation and decline in the parent aerobic biotransformation study by the OECD-RMS using a multi-compartmental model)	SYN521195	9.7–16.2 d	Non to slightly persistent	1348326
	SYN539678	19.7–36.9 d	Slightly persistent	1348326
	SUM of SYN536638/ SYN539679	5.8–18.3 d	Non to slightly persistent	1348326
	SYN504851	Maximum detected at study termination therefore DT50 cannot be calculated	Cannot be classified	1348326
	SYN500003	13.2–74.1 d	Non to moderately persistent	1348326
Biotransformation in anaerobic water systems	Mandipropamid	<p><u>Water: Simple 1st order and 1st order multi-compartment kinetics</u> DT₅₀ = 0.8–50.9 d DT₉₀ = 12.5–70.8 d</p> <p><u>Water: estimated 1st order t_{1/2}</u> 80th percentile = 26.1 d</p> <p><u>Sediment: simple 1st order kinetics</u> DT₅₀ = 5.4–15.2 d DT₉₀ = 17.2–48.4 d</p> <p><u>Sediment: 1st order t_{1/2}</u> 80th percentile = 13.3 d</p> <p><u>System: Simple 1st order kinetics</u> DT₅₀ = 6.0–22.8 d DT₉₀ = 19.4–74.7 d</p> <p><u>Sediment: 1st order t_{1/2}</u> 80th percentile = 18.2 d</p>	Mandipropamid is classified as non-persistent to slightly persistent under anaerobic conditions in the aquatic environment.*	1348333 1348335

Dissipation in anaerobic water/sediment system (calculated from the data obtained on the formation and decline in the parent aerobic biotransformation study by the OECD-RMS using a multi-compartmental model)	SYN521195	6.3–15.4 d	Non to slightly persistent	1348326
	SYN539678	12.0–23.0 d	Non to slightly persistent	1348326
	SUM of SYN536638/ SYN539679	3.7–33.0 d	Non to slightly persistent	1348326
	SYN504851	maximum detected at study termination therefore DT ₅₀ cannot be calculated	Cannot be classified	1348326
	SYN500003	23.0–34.2 d	Slightly persistent	1348326
Partitioning				
Adsorption/desorption in sediment	Mandipropamid	K _{OC} = 1479–1981	Information from water/sediment study Mandipropamid is classified as having low mobility ^b	1348333
Field studies				
Field dissipation (outdoor pond)	Mandipropamid	System DT ₅₀ = 5.4 d	Mandipropamid is non-persistent in an outdoor pond setting. ^a	1348334

^a Classified according to the classification scheme used in McEwen, F.L., and G.R. Stephenson. *The use and significance of pesticides in the environment*. Toronto: John Wiley and Sons Inc., 1979. 282 pp.

^b Classified according to the classification scheme used in McCall, J.P., D.A. Laskowski, R.L. Swann and J.J. Dishburger. (1981). Measurement of sorption coefficients of organic chemicals and their use in environmental fate analysis. Pages 89–109 in Test protocols for environmental fate and movement of toxicants. Proceedings of a symposium. Association of Official Analytical Chemists. 94th Annual Meeting, 21–22 October 1980 Washington, DC.

Table 10 Toxicity to Non-Target Terrestrial Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	Reference (PMRA #)
Invertebrates					
Earthworm	Acute	Mandipropamid	NOEC: 100 mg/kg soil dw (bw effect); EC ₅₀ : >1000 mg/kg soil dw	—	1348350
		CGA380778	NOEC: 100 mg/kg soil dw (bw effect); EC ₅₀ : >1000 mg/kg soil dw	—	1348349
Bee	Oral	Mandipropamid	LD ₅₀ : >200 µg a.i./bee	Relatively non-toxic	1348351
	Contact	Mandipropamid	LC ₅₀ : >160 µg a.i./bee	—	
Parasitic wasp	Contact	End-use product	48-h LR ₅₀ : = 827 g a.i./ha	—	1348327
Predatory mite	Contact	End-use product	7-d LR ₅₀ : >900 g a.i./ha	—	1348327
Birds					
Bobwhite quail	Acute	Mandipropamid	LD ₅₀ : >2250 mg a.i./kg bw	Practically non-toxic	1348363
	Dietary	Mandipropamid	LC ₅₀ : >6080 mg a.i./kg diet LD ₅₀ : >2141 mg a.i./kg bw/day NOEC: 3400 mg a.i./kg diet (bw effect) NOEL: 1448 mg a.i./kg bw/day	Practically non-toxic	1348365
	Reproduction	Mandipropamid	NOEC: 1060 mg a.i./kg diet NOEL: 83.6 mg a.i./kg bw/day (highest dose tested)	Reproductive effects are not expected below dietary concentrations of 1060 mg a.i./kg diet	1348367
Mallard duck	Acute	Mandipropamid	LD ₅₀ : >1000 mg a.i./kg bw NOEL: 1000 mg a.i./kg bw	Slightly toxic	1348364
	Dietary	Mandipropamid	LC ₅₀ : >6080 mg a.i./kg diet LD ₅₀ : >2856 mg a.i./kg bw/day NOEC: 3400 mg a.i./kg diet (bw effect) NOEL: 1222 mg a.i./kg bw/day	Practically non-toxic	1348366
	Reproduction	Mandipropamid	NOEC: 1050 mg a.i./kg diet NOEL: 158 mg a.i./kg bw/day	Reproductive effects are not expected below dietary concentrations of 1050 mg a.i./kg diet	1348368

Mammals					
Rat	Acute	Mandipropamid	LD ₅₀ : >5000 mg a.i./kg bw/day	Practically non-toxic	1348240
		SYN500003	LD ₅₀ : = 1049 mg a.i./kg bw/day	Slightly toxic	1457538
		Revus Fungicide	LD ₅₀ : >5000 mg a.i./kg bw/day	Low toxicity	1348157
	Dietary 90-d	Mandipropamid	LD ₅₀ : >5000 mg a.i./kg bw/day NOEL = 435 mg a.i./kg bw/day, based on decreased body weight and body-weight gain	Practically non-toxic	1348247
	Reproduction	Mandipropamid	NOEC = 250 mg a.i./kg diet NOEL = 22.9 mg a.i./kg bw/day; based on pup body weight	Effects on reproduction are not expected at or below 250 mg a.i./kg diet	1348259
Mouse	Dietary 28-d	Mandipropamid	LD ₅₀ : >7000 mg a.i./kg bw/day NOEL = 700 mg a.i./kg bw/day, based on decreased body weight and body-weight gain	Practically non-toxic	1348252 1348253
Vascular plants					
Vascular plant	Seedling emergence	End-use product	EC ₂₅ : >750 g a.i./ha.	No effects were noted on seedling emergence at the highest test application	1348314
	Vegetative vigour	End-use product	EC ₂₅ : >900 g a.i./ha	No effects were noted on vegetative vigour at the highest test application	1348315

^a Atkins et al. (1981) for bees and United States Environmental Protection Agency (USEPA) classification for others, where applicable

Table 11 Toxicity to Non-Target Aquatic Organisms

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity ^a	Reference (PMRA #)
Freshwater species					
<i>Daphnia magna</i>	Acute	Mandipropamid	48-h LC ₅₀ = 7.1 mg a.i./L	Moderately toxic	1348352
		CGA380778	48-h LC ₅₀ = 55.9 mg a.i./L	Slightly toxic	1348353
	Re-production	Mandipropamid	NOEC = 0.87 mg a.i./L, based on reproduction NOEC = 0.28 mg a.i./L, based on parent length	Effect on the timing in which the first brood appeared at the highest dose tested (2.64 mg a.i./L)	1348354
Rainbow trout	Acute	Mandipropamid	96-h LC ₅₀ = 4.4 mg a.i./L	Moderately toxic	1348358
		CGA380778	96-4 LC ₅₀ > 15.3 mg a.i./L	Not toxic at limit of solubility	1348357
Fathead minnow	Acute	Mandipropamid	96-h LC ₅₀ > 5.8 mg a.i./L	Not toxic at limit of solubility	1348360
	Early life stage	Mandipropamid	NOEC > 1.9 mg a.i./L; hatchability NOEC = 0.48 mg a.i./L, growth NOEC = 0.48 mg a.i./L, fry survival	—	1348361
<i>Pseudokirchneriella subcapitata</i>	Acute	Mandipropamid	EC ₅₀ > 2.5 mg a.i./L	—	1348317
		CGA380778	EC ₅₀ = 16 mg TGAI/L	—	1348313
		SYN504851	72-h E _b C ₅₀ = 26.7 mg/L 72-h E _r C ₅₀ = 36.9 mg/L	—	1348361
		SYN500003	72-h E _b C ₅₀ = 27.1 mg/L 72-h E _r C ₅₀ = 39.8 mg/L	—	1348361
		SYN536638	72-h E _b C ₅₀ > 5.5 mg/L 72-h E _r C ₅₀ > 5.5 mg/L	—	1348361
		NOA458422	72-h E _b C ₅₀ = 6.79 mg/L 72-h E _r C ₅₀ = 28.8 mg/L	—	1348361
<i>Anabaena flos-aquae</i>	Acute	Mandipropamid	96-h EC ₅₀ > 19.8 mg a.i./L	—	1348361
Vascular plant	Dissolved	Mandipropamid	EC ₅₀ > 4.3 mg a.i./L	—	1348316
Marine species					
Crustacean	Acute	Mandipropamid	96-h LC ₅₀ = 1.7 mg a.i./L	Moderately toxic	1348355
Mollusk	Acute	Mandipropamid	EC ₅₀ = 0.97 mg a.i./L (shell growth)	Highly toxic	1348356
Sheepshead minnow	Acute	Mandipropamid	96-h LC ₅₀ = 4.5 mg a.i./L	Moderately toxic	1348359

^a USEPA classification, where applicable.

Table 12 Screening Level Risk Assessment for Terrestrial Organisms Other Than Birds and Mammals

Organism	Exposure	Endpoint value ^a	EEC ^c	RQ ^d	LOC ^e exceeded
Invertebrates					
Earthworm	Acute: Mandipropamid	LC _{50/2} >500 mg a.i./kg soil	0.244 mg a.i./kg soil	<0.5	No
	Acute: CGA380778	LC _{50/2} >500 mg a.i./kg soil	0.19 mg a.i./kg soil	<0.5	No
Bee	Contact: Mandipropamid	LC ₅₀ >200 µg a.i./bee (>224 kg a.i./ha ^b)	150 g a.i./ha	<0.75	No
	Oral: Mandipropamid	LC ₅₀ >160 µg a.i./bee (>179.2 kg a.i./ha ^b)	150 g a.i./ha	<0.9	No
Predatory mites and spidermites	Contact: end-use product (EUP)	No effects after 4 applications at rates up to 240 g a.i./ha (= 960 g a.i./ha)	600 g a.i./ha	0.6	No
Parasitic wasp	Contact: EUP	LR ₅₀ = 827 g a.i./ha	600 g a.i./ha	0.7	No
Vascular plants					
Vascular plant	Seedling emergence	EC ₂₅ >750 g a.i./ha	600 g a.i./ha ^f	0.8	No
	Vegetative vigour	EC ₂₅ >900 g a.i./ha		0.7	No

^a Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e. protection at the community, population or individual level).

^b Toxicity in µg/bee converted to the equivalent kg a.i./ha using a conversion factor of 1.12 (Atkins et al., 1981).

^c Environmental Exposure Concentration (Soil: calculated based on a soil density of 1.5 g/cm³, soil depth of 15 cm and the label rates, taking into consideration dissipation between applications; Bee: maximum individual application rate; Parasitic wasp and vascular plants: maximum application rate not taking into consideration dissipation between applications).

^d Risk Quotient (RQ) = exposure/toxicity.

^e Level of Concern (LOC) = RQ = 1; a calculated RQ >1 exceeds the LOC.

^f The maximum seasonal rate proposed for registration in Canada is 600 g a.i./ha (4 × 150 mg a.i./ha), does not take into consideration dissipation between applications.

Table 13 Screening Level Risk Assessment for Birds and Mammals

Organism	Exposure	Endpoint value ^a	Feeding Guilds	Exposure ^d		RQ ^e	LOC exceeded
				EEC (mg a.i./kg diet)	EDE (mg a.i./kg bw)		
Birds							
Bird weight: 20 g	Acute: Mandipropamid	LD ₅₀ /10 >100 mg a.i./kg bw	Insectivore	97.5	24.9	0.25	No
			Granivore	16.7	4.3	<0.1	No
			Frugivore	50.2	12.8	0.13	No
	Dietary: Mandipropamid	5-d LD ₅₀ /10 >214.1 mg a.i./kg bw ^b	Insectivore	97.5	24.9	<0.1	No
			Granivore	16.7	4.3	<0.1	No
			Frugivore	50.2	12.8	<0.1	No
	Reproduction: Mandipropamid	NOEL = 83.6 mg a.i./kg bw/day ^c	Insectivore	97.5	24.9	0.3	No
			Granivore	16.7	4.3	<0.1	No
			Frugivore	50.2	12.8	0.15	No
Bird weight: 100 g	Acute: Mandipropamid	LD ₅₀ /10 >100 mg a.i./kg bw	Insectivore	97.5	19.4	0.19	No
			Granivore	16.7	3.3	<0.1	No
			Frugivore	50.2	10.0	0.1	No
	Dietary	5-d LD ₅₀ /10 >214.1 mg a.i./kg bw ^b	Insectivore	97.5	19.4	<0.1	No
			Granivore	16.7	3.3	<0.1	No
			Frugivore	50.2	10.0	<0.1	No
	Reproduction: Mandipropamid	NOEL = 83.6 mg a.i./kg bw/day ^c	Insectivore	97.5	19.4	0.23	No
			Granivore	16.7	3.3	<0.1	No
			Frugivore	50.2	10.0	0.12	No
Bird weight: 1000 g	Acute: Mandipropamid	LD ₅₀ /10 >100 mg a.i./kg bw	Insectivore	97.5	5.7	<0.1	No
			Granivore	16.7	0.9	<0.1	No
			Frugivore	50.2	2.9	<0.1	No
			Herbivore	607.7	35.3	<0.35	No
	Dietary	5-d LD ₅₀ /10 >214.1 mg a.i./kg bw ^b	Insectivore	97.5	5.7	<0.1	No
			Granivore	16.7	0.9	<0.1	No
			Frugivore	50.2	2.9	<0.1	No
			Herbivore	607.7	35.3	<0.17	No
	Reproduction: Mandipropamid	NOEL = 83.6 mg a.i./kg bw/day ^c	Insectivore	97.5	5.7	<0.1	No
			Granivore	16.7	0.9	<0.1	No
			Frugivore	50.2	2.9	<0.1	No
			Herbivore	607.7	35.3	0.42	No

Mammals							
Mammal weight: 0.015 kg	Acute: Mandipropamid	LD ₅₀ /10 >500 mg a.i./kg bw	Insectivore	97.5	14.2	<0.1	No
			Granivore	16.7	2.4	<0.1	No
			Frugivore	50.2	7.3	<0.1	No
	Acute: SYN500003	LD ₅₀ /10 = 104.9 mg a.i./kg bw	Insectivore	97.5	14.2	0.28	No
			Granivore	16.7	2.4	<0.1	No
			Frugivore	50.2	7.3	<0.1	No
	Dietary: Mandipropamid	90-d LD ₅₀ /10 >43.5 mg a.i./kg bw/day ^c	Insectivore	97.5	14.2	<0.3	No
			Granivore	16.7	2.4	<0.1	No
			Frugivore	50.2	7.3	<0.2	No
	Reproduction: Mandipropamid	NOEL = 22.9 mg a.i./kg bw/day ^c	Insectivore	97.5	14.2	0.62	No
			Granivore	16.7	2.4	0.1	No
			Frugivore	50.2	7.3	0.3	No
Mammal weight: 0.035 kg	Acute: Mandipropamid	LD ₅₀ /10 >500 mg a.i./kg bw	Insectivore	97.5	12.2	<0.1	No
			Granivore	16.7	2.1	<0.1	No
			Frugivore	50.2	6.3	<0.1	No
			Herbivore	607.7	75.9	<0.1	No
	Acute: SYN500003	LD ₅₀ /10 = 104.9 mg a.i./kg bw	Insectivore	97.5	12.2	<0.1	No
			Granivore	16.7	2.1	<0.1	No
			Frugivore	50.2	6.3	<0.1	No
			Herbivore	607.7	75.9	0.7	No
	Dietary: Mandipropamid	90-d LD ₅₀ /10 >43.5 mg a.i./kg bw/day ^c	Insectivore	97.5	12.2	<0.3	No
			Granivore	16.7	2.1	<0.1	No
			Frugivore	50.2	6.3	<0.14	No
			Herbivore	607.7	75.9	<1.7	No
	Reproduction: Mandipropamid	NOEL = 22.9 mg a.i./kg bw/day ^c	Insectivore	97.5	12.2	0.5	No
			Granivore	16.7	2.1	0.1	No
			Frugivore	50.2	6.3	0.3	No
			Herbivore	607.7	75.9	3.3	Yes
Mammal weight: 1 kg	Acute: Mandipropamid	LD ₅₀ /10 >500 mg a.i./kg bw	Insectivore	97.5	6.7	<0.1	No
			Granivore	16.7	1.2	<0.1	No
			Frugivore	50.2	3.5	<0.1	No
			Herbivore	607.7	41.8	<0.1	No
	Acute: SYN500003	LD ₅₀ /10 = 104.9 mg a.i./kg bw	Insectivore	97.5	6.7	<0.1	No
			Granivore	16.7	1.2	<0.1	No
			Frugivore	50.2	3.5	<0.1	No
			Herbivore	607.7	41.8	0.38	No

	Dietary: Mandipropamid	90-d LD ₅₀ /10 >43.5 mg a.i./kg bw/day ^e	Insectivore	97.5	6.7	<0.15	No
			Granivore	16.7	1.2	<0.1	No
			Frugivore	50.2	3.5	<0.1	No
			Herbivore	607.7	41.8	<0.9	No
	Reproduction: Mandipropamid	NOEL = 22.9 mg a.i./kg bw/day ^e	Insectivore	97.5	6.7	0.3	No
			Granivore	16.7	1.2	<0.1	No
			Frugivore	50.2	3.5	0.1	No
			Herbivore	607.7	41.8	1.8	Yes

^a Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e. protection at the community, population, or individual level).

^b 5-day LD₅₀ – conversion of 5-day LC₅₀ from a concentration to a dose [5-day LD₅₀ (mg a.i./kg bw) = LC₅₀ (mg a.i./kg diet)/BW (g) × FIR (g diet/day)].

^c NOEL obtained from study.

^d EEC: For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994).

EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/BW) × EEC. For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy, K.A. Field metabolic rate and food requirement scaling in mammals and birds. *Ecological Monographs* 57: 1987, pp. 111–128. For generic birds with body weight less than or equal to 200 g, the “passerine” equation was used; for generic birds with body weight greater than 200 g, the “all birds” equation was used; for mammals, the “all mammals” equation was used:

Passerine Equation (body weight <or =200 g): FIR (g dry weight/day) = 0.398(BW in g) 0.850

All Birds Equation (body weight >200 g): FIR (g dry weight/day) = 0.648(BW in g) 0.651

All Mammals Equation: FIR (g dry weight/day) = 0.235(BW in g) 0.822

^e RQ = exposure/toxicity; RQs <0.1 were not calculated to show all decimal points

Table 14 Screening Level Risk Assessment for Aquatic Organisms


Organism	Exposure	Substance	Endpoint value ^a	EEC ^b mg a.i./L	RQ	LOC exceeded
Freshwater species						
<i>Daphnia magna</i>	Acute	Mandipropamid	48-h EC ₅₀ /2 = 3.55 mg a.i./L	0.06	<0.1	No
		CGA380778	48-h EC ₅₀ /2 = 27.9 mg a.i./L	Not environmentally relevant; therefore, a RQ was not calculated, not considered of concern to aquatic organisms		
	Reproduction	Mandipropamid	NOEC = 0.87 mg a.i./L, reproductive effects	0.06	<0.1	No
			NOEC = 0.28 mg a.i./L, parental effects	0.06	0.2	No
Rainbow trout	Acute	Mandipropamid	96-h LC ₅₀ /10 = 0.4 mg a.i./L	0.06	0.15	No
		CGA380778	96-h LC ₅₀ /10 > 4.3 mg TGA/L	Not environmentally relevant; therefore, a RQ was not calculated, not considered of concern to aquatic organisms		
Fathead minnow	Acute	Mandipropamid	96-h LC ₅₀ /10 > 0.58 mg a.i./L	0.06	0.1	No
	Chronic (early life-stage)	Mandipropamid	NOEC > 1.9 mg a.i./L; hatchability	0.06	<0.1	No
			NOEC = 0.48 mg a.i./L; growth & fry survival	0.06	0.13	No
<i>Pseudokirchneriella subcapitata</i>	Acute	Mandipropamid	EC ₅₀ /2 > 1.25 mg a.i./L	0.06	<0.1	No
		CGA380778	EC ₅₀ /2 = 7.65 mg TGA/L	Not environmentally relevant; therefore, a RQ was not calculated, not considered of concern to aquatic organisms		
		SYN504851	72-h E _b C ₅₀ /2 = 13.4 mg/L 72-h E _r C ₅₀ /2 = 18.5 mg/L	0.03	<0.1	No
		SYN500003	72-h E _b C ₅₀ /2 = 13.6 mg/L 72-h E _r C ₅₀ /2 = 19.9 mg/L	0.03	<0.1	No
		SYN536638	72-h E _b C ₅₀ /2 > 2.8 mg/L 72-h E _r C ₅₀ /2 > 2.8 mg/L	0.06	<0.1	No
		NOA458422	72-h E _b C ₅₀ /2 = 3.4 mg/L 72-h E _r C ₅₀ /2 = 14.4 mg/L	Not environmentally relevant; therefore, a RQ was not calculated, not considered of concern to aquatic organisms		
<i>Anabaena flos-aquae</i>	Acute	Mandipropamid	96-h EC ₅₀ /2 > 9.9 mg a.i./L	0.06	<0.1	No
Vascular plant	Dissolved	Mandipropamid	EC ₅₀ /2 > 2.2 mg a.i./L	0.06	<0.1	No

Amphibians						
Amphibians	Acute	Mandipropamid	96-h LC ₅₀ /10 = 0.4 mg a.i./L	0.3	0.75	No
	Chronic	Mandipropamid	NOEC = 0.48 mg a.i./L; fry survival	0.3	0.63	No
Marine species						
Crustacean	Acute	Mandipropamid	96-h LC ₅₀ /10 = 0.17 mg a.i./L	0.06	0.35	No
Mollusk	Acute	Mandipropamid	EC ₅₀ /10 = 0.097 mg a.i./L (shell growth)	0.06	0.62	No
Sheepshead minnow	Acute	Mandipropamid	96-h LC ₅₀ /10 = 0.45 mg a.i./L	0.06	0.13	No

^a Endpoints were divided by an Uncertainty Factor to account for varying protection goals (i.e. protection at the community, population or individual level).

^b EECs for aquatic systems were calculated assuming a reasonable conservative scenario of direct application into water bodies at two different depths (80 cm and 15 cm). The 80 cm water body is chosen to represent a permanent body of water and 15 cm is chosen to represent a seasonal body of water. EECs for transformation products assumed 100% conversion to the transformation product, adjusted for molecular weight (SYN504851 and SYN500003 have the same chemical formula—molecular weight = 226.66 g/mol; SYN536638 has the same chemical formula as mandipropamid—molecular weight = 411.9 g/mol).

Table 15 Refined Risk Assessments for Small Mammals

Organisms	Type of Exposure: Test Substance	Toxicity	Feeding Guild	Refined Exposure (mg a.i./kg bw)		RQ	>LOC
				EEC ^a	EDE ^c		
Mammal weight: 0.035 kg		NOEL = 22.9 mg a.i./kg bw/day ^b	Herbivore (leaves, leafy crops)	Off-field assessment			
				411.7	With 11% drift deposition: 5.7	0.3	No
					With 23% drift deposition: 11.87	0.52	No
			Herbivore (short grass – additional food type) ^d	In-field assessment ^b			
				236.01	29.5	1.3	Yes
				Off-field assessment			
				236.01	With 11% drift deposition: 3.2	0.14	No
					With 23% drift deposition: 6.8	0.52	No
				Herbivore (long grass – additional food type) ^d	In-field assessment ^b		
			144.1		17.9	0.8	No
			Off-field assessment				
			144.1		With 11% drift deposition: 1.9	0.1	No
					With 23% drift deposition: 4.1	0.18	No
Mammals weight: 1 kg	Reproduction: Mandipropamid	NOEL = 22.9 mg a.i./kg bw/day ^b	Herbivore (leaves, leafy crops)		Off-field assessment		
				411.7	With 11% drift deposition: 3.1	0.14	No
					With 23% drift deposition: 6.5	<0.1	No
			Herbivore (short grass – additional food type) ^d	In-field assessment ^b			
				236	16.2	0.71	No
				Off-field assessment			
				236	With 11% drift deposition: 1.8	<0.1	No
					With 23% drift deposition: 3.7	0.16	No
				Herbivore (long grass – additional food type) ^d	In-field assessment ^b		
			144.1		9.9	0.4	No
			Off-field assessment				
			144.1		With 11% drift deposition: 1.1	<0.1	No
					With 23% drift deposition: 2.3	0.1	No

^a The EEC was calculated using a half-life of 10 days rather than 35 days used in the screening level risk assessment.

^b In-field assessment assumes 100% contamination of the food source immediately after the final application. The assessment was conducted to take into consideration other food sources for herbivores.

^c EDE takes into consideration spray deposition rates of 11% for ground application and 23% for aerial applications at 1 m downwind from the site of application.

^d Different food type than at screening level.

Table 16 Summary of Alternatives

Crop	Disease	Active and FRAC Fungicide Group
Brassica Head and Stem subgroup: Broccoli, Chinese broccoli (gailon), Brussels sprouts, cabbage, Chinese cabbage (napa), Chinese mustard, cabbage (gai choy), cauliflower, cavalo broccoli, kohlrabi Leafy Greens subgroup: Broccoli raab, cabbage, Chinese collards, kale, mizuna, mustard greens, mustard spinach, rape greens, including all cultivars and/or hybrids of these	Downy mildew (<i>Peronospora parasitica</i>)	<i>Bacillus subtilis</i> (N/A) Chlorothalonil (Group M5) Fosetyl-al (Group 33) Zineb (Group M3)
Bulb Vegetables (Dry bulbs): Onion, bulb, garlic, shallot Green Onions: Green onions, leek, welch onion	Downy mildew (<i>Peronospora destructor</i>)	<i>Bacillus subtilis</i> (N/A) Boscalid (Group 7) Copper (Group M1) Fosetyl-al (Group 33) Maneb (Group M3) Metalaxyl-M (Group 4) Mancozeb (Group M3) Pyraclostrobin (Group 11)
Cucurbits: Cantaloupe, Chayote, Chinese-waxgourd, field cucumber, gourds, honeydew, melons <i>Momordica</i> spp. (bitter melon, balsam apple), muskmelon, watermelon, pumpkin, squash, zucchini	Downy mildew (<i>Pseudo-peronospora cubensis</i>)	Chlorothalonil (Group M5) Copper (Group M1) Cyazofamid (Group 21) Folpet (Group M4) Mancozeb (Group M3) Maneb (Group M3) Pyraclostrobin (Group 11)
Fruiting Vegetables: Bell peppers, non-Bell peppers	Phytophthora blight (<i>Phytophthora capsici</i>)	None
Field Tomato: Tomatillo	Late blight (<i>Phytophthora infestans</i>)	Boscalid (Group 7) Captan (Group M4) Chlorothalonil (Group M5) Copper (Group M1) Mancozeb (Group M3) Maneb (Group M3) Metiram (Group M3) Pyraclostrobin (Group 11) Ziram (Group M3)

Crop	Disease	Active and FRAC Fungicide Group
Grapes	Downy mildew (<i>Plasmopara viticola</i>)	Azoxystrobin (Group 11) Captan (Group M4) Copper (Group M1) Folpet (Group M4) Kresoxim-methyl (Group 11) Metalaxyl-M (Group 4) Mancozeb (Group M3) Metiram (Group M3) Zoxamide (Group 22)
Potatoes	Late blight (<i>Phytophthora infestans</i>)	Boscalid (Group 7) Captan (Group M4) Chlorothalonil (Group M5) Copper (Group M1) Cymoxanil (Group 27) Dimethomorph (Group 40) Fenamidone (Group 11) Fluazinam (Group 29) Mancozeb (Group M3) Maneb (Group M3) Metalaxyl-M (Group 4) Metiram (Group M3) Propamocarb HCl (Group 28) Zoxamide (Group 22)
Leafy Vegetables: Field lettuce, leaf and head, spinach	Downy mildew (<i>Bremia lactucae</i>) Blue mould (<i>Peronospora effusa</i>)	<i>Bacillus subtilis</i> (N/A) Fosetyl-al (Group 33) Metalaxyl-M (Group 4) Mancozeb (Group M3) Quadris (spinach only – Group 11) Zineb (Group M3)

Table 17 Use Claims (i.e. Label Claims) Proposed by Applicant and Whether Claims Are Acceptable or Unsupported

Proposed Claims		Accepted Value and Sustainability Assessment Directorate Claims
Crops	Diseases, Rates, Use Pattern	
<p>Brassica</p> <p>Head and Stem subgroup: Broccoli, Chinese broccoli (gailon), Brussels sprouts, cabbage, Chinese cabbage (napa), Chinese mustard, cabbage (gai choy), cauliflower, cavalo broccoli, kohlrabi</p> <p>Leafy Greens subgroup: Broccoli raab, cabbage, Chinese collards, kale, mizuna, mustard greens, mustard spinach, rape greens</p>	<p>Diseases: control of Downy mildew (<i>Peronospora parasitica</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7–10 day interval.</p> <p>The use of silicone-based adjuvants (0.25% v/v) is recommended.</p> <p>Apply by ground or air.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Crops</u>: The Head and Stem sub-group crops are fully supported, and the leafy greens subgroup are conditionally supported.</p> <p><u>Use Pattern</u>: Instead of a silicone-based adjuvant, it is recommended to use a non-ionic surfactant at 0.125% v/v.</p> <p>A maximum of four applications per season may be made for resistance-management reasons.</p>
<p>Bulb Vegetables</p> <p>Dry bulb: Onion, bulb, garlic, shallot</p> <p>Green Onion: Green onions, leek, Welch onion</p>	<p>Diseases: control of Downy mildew (<i>Peronospora destructor</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7–10 day interval.</p> <p>The use of silicone-based adjuvants (0.25% v/v) is recommended.</p> <p>Apply by ground or air.</p> <p>For dry bulb vegetables, a max of 2.3 L/ha (575 g a.i./ha) may be applied. For green onions, do not apply more than 1.75 L/ha/season (439 g a.i./ha/season).</p>	<p>Supported as proposed with the following changes:</p> <p><u>Crops</u>: The dry bulb crops were fully supported. The green onion crops (green onions, leek, Welch onion) were conditionally supported.</p> <p><u>Rate</u>: The 400 mL rate is supported; the 600 mL rate is conditionally supported</p> <p><u>Use pattern</u>: Apply prior to disease development, and continue on a 7 day interval (instead of 7–10 day interval).</p> <p>Instead of a silicone-based adjuvant, it is recommended to use a non-ionic surfactant at 0.125% v/v, or mineral oil at 1.0% v/v.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p>

Proposed Claims		Accepted Value and Sustainability Assessment Directorate Claims
Crops	Diseases, Rates, Use Pattern	
<p>Cucurbits: Cantaloupe, Chayote, Chinese-waxgourd, field cucumber, gourds, honeydew, melons <i>Momordica</i> spp. (bitter melon, balsam apple), muskmelon, watermelon, pumpkin, squash, zucchini, including cultivars and/or hybrids of these</p> <p>Greenhouse cucumbers (For use in greenhouse only – not for transplant to the field)</p>	<p>Diseases: Suppression of Downy mildew (<i>Pseudoperonospora cubensis</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7–10 day interval.</p> <p>The use of non-ionic surfactants (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>A maximum of 2.3 L/ha (575 g a.i./ha) may be applied per season.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Use pattern:</u> it is recommended to use a non-ionic surfactant at 0.125% v/v.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p> <p>For resistance management purposes, do not apply Revus Fungicide to greenhouse-grown seedlings to be transplanted into the field until after they have been transplanted-out.</p> <p>It is necessary to add a phytotoxicity warning statement to the label (warning statement was provided by the registrant).</p>
<p>Fruiting Vegetables:</p> <p>Field peppers: Bell peppers, non-Bell peppers, sweet non-Bell peppers</p> <p>Eggplant Okra Groundcherry Pepino</p> <p>Greenhouse peppers</p>	<p>Disease: Suppression of phytophthora blight (<i>Phytophthora capsici</i>)</p> <p>Rates: 600 mL/ha (150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7–10 day interval.</p> <p>The use of a non-ionic surfactant (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>Do not apply more than 2.3 L product/season (585 g a.i./ha).</p>	<p>Conditionally supported with the following major changes:</p> <p><u>Crops supported:</u> Field pepper transplants</p> <p>For use on peppers to be treated in the greenhouse and immediately transplanted to the field, including: Bell peppers, non-Bell peppers and sweet non-Bell peppers</p> <p><u>Use pattern:</u> Make one application of Revus Fungicide as a drench immediately before transplanting to the field.</p> <p>The use of a non-ionic adjuvant (0.125%) is recommended.</p> <p>For resistance management purposes make no more than one application per season.</p>

Proposed Claims		Accepted Value and Sustainability Assessment Directorate Claims
Crops	Diseases, Rates, Use Pattern	
Grapes	<p>Disease: control of Downy mildew (<i>Plasmopara viticola</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7 day interval.</p> <p>The use of non-ionic surfactants (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>A maximum of 2.3 L/ha (575 g a.i./ha) may be applied.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Rates</u>: 500 mL/ha (125 g a.i./ha)</p> <p><u>Use pattern</u>: Apply prior to disease development, and continue on a 7 to 10 day interval.</p> <p>The use of a non-ionic surfactant (0.125% v/v) is recommended.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p>
Field Tomato, tomatillo Greenhouse tomatoes (For use in greenhouse only – not for transplant to the field)	<p>Disease: control of Late blight (<i>Phytophthora infestans</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7–10 day interval.</p> <p>The use of a non-ionic surfactant (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>Do not apply more than 2.3 L product/season (585 g a.i./ha).</p>	<p>Supported as proposed with the following changes:</p> <p><u>Use pattern</u>: it is recommended to use a non-ionic surfactant at 0.125% v/v.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p> <p>For resistance management purposes, do not apply Revus Fungicide to greenhouse-grown seedlings to be transplanted into the field until after they have been transplanted-out.</p>

Proposed Claims		Accepted Value and Sustainability Assessment Directorate Claims
Crops	Diseases, Rates, Use Pattern	
<p>Root and Tuber Vegetables</p> <p>Tuberous and corm subgroup:</p> <p>Arracacha, arrowroot, Chinese and Jerusalem artichoke, burdock, canna, edible bitter and sweet cassava, chayote (root), chufa, dasheen (Taro), ginger, leren, potato, sweet potato, taniar, turmeric, yam (bean), yam (true)</p>	<p>Disease: control of Late blight (<i>Phytophthora infestans</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7 day interval.</p> <p>The use of non-ionic surfactants (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>A maximum of 2.3 L/ha (575 g a.i./ha) may be applied.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Crop</u>: only potatoes are supported.</p> <p><u>Use pattern</u>: Apply prior to disease development, and continue on a 7- to 10-day interval.</p> <p>The use of a non-ionic surfactant (0.125% v/v) is recommended.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p>
<p>Leafy Vegetables:</p> <p>Field lettuce, leaf and head, spinach</p> <p>Greenhouse lettuce (For use in greenhouse only – not for transplant to the field)</p>	<p>Disease: control of Downy mildew (<i>Bremia lactucae</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7-day interval.</p> <p>The use of non-ionic surfactants (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>A maximum of 2.3 L/ha (575 g a.i./ha) may be applied.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Use pattern</u>: Apply prior to disease development, and continue on a 7 to 10 day interval.</p> <p>The use of a non-ionic surfactant (0.125% v/v) is recommended.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p> <p>For resistance management purposes, do not apply Revus Fungicide to greenhouse-grown seedlings to be transplanted into the field until after they have been transplanted-out.</p>

Proposed Claims		Accepted Value and Sustainability Assessment Directorate Claims
Crops	Diseases, Rates, Use Pattern	
<p>Leafy Vegetables:</p> <p>Field lettuce, leaf and head, spinach</p> <p>Greenhouse lettuce (For use in greenhouse only – not for transplant to the field)</p>	<p>Disease: control of Downy mildew also known as Blue mould (<i>Peronospora effusa</i>)</p> <p>Rates: 400–600 mL/ha (100–150 g a.i./ha)</p> <p>Use pattern: Apply prior to disease development, and continue on a 7-day interval.</p> <p>The use of non-ionic surfactants (0.25% v/v) is recommended.</p> <p>Apply by ground or air (field use).</p> <p>A maximum of 2.3 L/ha (575 g a.i./ha) may be applied.</p>	<p>Supported as proposed with the following changes:</p> <p><u>Use pattern</u>: Apply prior to disease development, and continue on a 7 to 10 day interval.</p> <p>The use of a non-ionic surfactant (0.125% v/v) is recommended.</p> <p>Instead of stating a maximum amount of product per ha per season, it is recommended that a maximum of four applications per season may be made for resistance management.</p> <p>For resistance management purposes, do not apply Revus Fungicide to greenhouse-grown seedlings to be transplanted into the field, until after they have been transplanted-out.</p>
Aerial application on field crops (minimum of 45 L water as carrier volume).	For the supported field crops on the Revus Fungicide label.	Supported as proposed.
Tank mix with Bravo 500 Agricultural Fungicide for all field crops (not greenhouse crops)	For the supported field crops on the Revus Fungicide label, a tank mix with Bravo 500 Agricultural Fungicide at labelled rates for resistance management and broader spectrum of disease control.	Supported as proposed for crops that are already listed on the Bravo 500 Agricultural Fungicide label, including: broccoli, Brussels sprouts, cabbage, cauliflower, cucumbers, cantaloup, muskmelon, honeydew, watermelons, squash, pumpkin, dry bulb onions, green bunching onions, potatoes, tomatoes.

Appendix II Supplemental Maximum Residue Limit Information— International Situation and Trade Implications

The Canadian MRLs on the following crops and crop groups are the same as those in the American *Electronic Code of Federal Regulations*:

- Vegetable, Brassica, head and stem, crop subgroup 5A;
- Vegetable, Brassica, leafy greens, crop subgroup 5B;
- Vegetable, cucurbit, crop group 9;
- Vegetable, leafy except Brassica, crop group 4;
- Vegetable, fruiting, crop group 8;
- Vegetable, tuberous and corm, crop subgroup 1C;
- Grape;
- Grape, raisin;
- Bulb onion subgroup 3-07A;
- Green onion subgroup 07B; and
- Okra.

Currently, no Codex MRLs have been established for mandipropamid on any commodity (www.mrldatabase.com).

Appendix III Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
1C	Root and tuber vegetables Tuberous and corm vegetables subgroup	Arracacha Arrowroot Cassava roots Chayote roots Chinese artichokes Chufa Edible canna Ginger roots Jerusalem artichokes Lerens Potatoes Sweet potato roots Tanier corms Taro corms True yam tubers Turmeric roots Yam bean roots
3-07A	Bulb vegetables Bulb onion subgroup	Chinese onions Daylilies Dry bulb onions Fritillaria bulbs Garlic Great headed garlic Lilies Pearl onions Potato onions Serpent garlic Shallot bulbs
3-07B	Bulb vegetables Green onion subgroup	Beltsville bunching onions Elegans hosta Fresh Chinese chive leaves Fresh chive leaves Fresh onions Fritillaria leaves Green onions Kurrats Lady's leeks Leeks Macrostem onions Shallot leaves

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
		Tree onion tops Welsh onion tops Wild leeks
4	Leafy vegetables (except <i>Brassica</i> vegetables)	Amaranth Arugula Cardoon Celery Celtuce Chinese celery Corn salad Dandelion leaves Dock Edible leaved chrysanthemum Endives Fresh chervil leaves Fresh Florence fennel leaves and stalk Fresh parsley leaves Garden cress Garden purslane Garland chrysanthemum Head lettuce Leaf lettuce New Zealand spinach Orach leaves Radicchio Rhubarb Spinach Swiss chard Upland cress Vine spinach Winter purslane
5A	<i>Brassica</i> (cole) leafy vegetables Head and stem <i>Brassica</i> subgroup	Broccoli Brussels sprouts Cabbages Cauliflower Chinese broccoli Chinese mustard cabbages Kohlrabi Napa Chinese cabbages
5B	<i>Brassica</i> (cole) leafy vegetables Leafy <i>Brassica</i> greens subgroup	Bok choy Chinese cabbages Broccoli raab Collards

Crop Group Number	Name of the Crop Group	Food Commodities Included in the Crop Group
		Kale Mustard greens Mustard spinach Rape greens
8	Fruiting vegetables (except cucurbits)	Bell peppers Eggplants Groundcherries Non-Bell peppers Pepinos Pepper hybrids Tomatillos Tomatoes
9	Cucurbit vegetables	Balsam apples Balsam pears Cantaloupes Chayote fruit Chinese cucumbers Chinese waxgourds Citron melons Cucumbers Edible gourds (other than those listed in this item) Muskmelons (other than those listed in this item) Pumpkins Summer squash Watermelons West Indian gherkins Winter squash

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4.0 Value

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- 1517466 2006, Evaluation of compounds for efficacy against *Phytophthora capsici* in bell pepper, fall 2006: DACO: 10.2.3
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- 1374714 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-BHS-03 - Brassica Head and Stem Subgroup, DACO: 10.2.3.3
- 1374715 2005, 10.2.3.3 - Efficacy Trial - 2005-DM-BHS-01 - Brassica Head and Stem Subgroup, DACO: 10.2.3.3
- 1374716 2005, 10.2.3.3 - Efficacy Trial - 2005-DM-BHS-02 - Brassica Head and Stem Subgroup, DACO: 10.2.3.3
- 1374717 2006, 10.2.3.3 - Efficacy Trial - 2006-DM-BHS-01 - Brassica Head and Stem Subgroup, DACO: 10.2.3.3
- 1374718 2005, 10.2.3.3 - Efficacy Trial - 2004-DM-BV-01 - Bulb Vegetables, DACO: 10.2.3.3
- 1374719 2005, 10.2.3.3 - Efficacy Trial - 2004-DM-BV-02 - Bulb Vegetables, DACO: 10.2.3.3
- 1374720 2005, 10.2.3.3 - Efficacy Trial - 2005-DM-BV-01 - Bulb Vegetables, DACO: 10.2.3.3
- 1374721 2003, 10.2.3.3 - Efficacy Trial - 2002-DM-CU-01 - Cucurbits, DACO: 10.2.3.3
- 1374722 2003, 10.2.3.3 - Efficacy Trial - 2002-DM-CU-02 - Cucurbits, DACO: 10.2.3.3
- 1374723 2002, 10.2.3.3 - Efficacy Trial - 2002-DM-CU-03 - Cucurbits, DACO: 10.2.3.3
- 1374724 2002, 10.2.3.3 - Efficacy Trial - 2002-DM-CU-04 - Cucurbits, DACO: 10.2.3.3
- 1374725 2003, 10.2.3.3 - Efficacy Trial - 2003-DM-CU-01 - Cucurbits, DACO: 10.2.3.3
- 1374726 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-CU-01 - Cucurbits, DACO: 10.2.3.3
- 1374727 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-CU-02 - Cucurbits, DACO: 10.2.3.3
- 1374728 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-CU-03 - Cucurbits, DACO: 10.2.3.3
- 1374729 2006, 10.2.3.3 - Efficacy Trial - 2006-DM-CU-01 - Cucurbits, DACO: 10.2.3.3
- 1374730 2006, 10.2.3.3 - Efficacy Trial - 2006-PB-CU-01 - Cucurbits, DACO: 10.2.3.3
- 1374731 2007, 10.2.3.3 - Efficacy Trial - 2006-PB-CU-02 - Cucurbits, DACO: 10.2.3.3
- 1374732 2003, 10.2.3.3 - Efficacy Trial - 2003-PB-FV-01 - Fruiting Vegetables, DACO: 10.2.3.3
- 1374733 2004, 10.2.3.3 - Efficacy Trial - 2004-PB-FV-01 - Fruiting Vegetables, DACO: 10.2.3.3
- 1374734 2005, 10.2.3.3 - Efficacy Trial - 2005-PB-FV-01 - Fruiting Vegetables, DACO: 10.2.3.3
- 1374735 2005, 10.2.3.3 - Efficacy Trial - 2005-PB-FV-02 - Fruiting Vegetables, DACO: 10.2.3.3
- 1374736 2006, 10.2.3.3 - Efficacy Trial - 2006-PB-FV-01 - Fruiting Vegetables, DACO: 10.2.3.3
- 1374737 2002, 10.2.3.3 - Efficacy Trial - 2002-DM-G-01 - Grapes, DACO: 10.2.3.3
- 1374738 2002, 10.2.3.3 - Efficacy Trial - 2002-DM-G-02 - Grapes, DACO: 10.2.3.3
- 1374739 2001, 10.2.3.3 - Efficacy Trial - 2001-DM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3

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- 1374740 2002, 10.2.3.3 - Efficacy Trial - 2002-DM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3
- 1374741 2004, 10.2.3.3 - Efficacy Trial - 2004-BM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3
- 1374742 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3
- 1374743 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-LV-02 - Leafy Vegetables, DACO: 10.2.3.3
- 1374744 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-LV-03 - Leafy Vegetables, DACO: 10.2.3.3
- 1374745 2005, 10.2.3.3 - Efficacy Trial - 2005-DM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3
- 1374746 2006, 10.2.3.3 - Efficacy Trial - 2006-DM-LV-01 - Leafy Vegetables, DACO: 10.2.3.3
- 1374747 2006, 10.2.3.3 - Efficacy Trial - 2006-DM-LV-02 - Leafy Vegetables, DACO: 10.2.3.3
- 1374748 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-GH-CU-01 - Greenhouse Cucumbers, DACO: 10.2.3.3
- 1374749 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-GH-CU-02 - Greenhouse Cucumbers, DACO: 10.2.3.3
- 1374750 2004, 10.2.3.3 - Efficacy Trial - 2004-DM-GH-CU-03 - Greenhouse Cucumbers, DACO: 10.2.3.3
- 1374751 2004, 10.2.3.3 - Efficacy Trial - 2004-LB-GH-TOM-01 - Greenhouse Tomatoes, DACO: 10.2.3.3
- 1374752 2006, 10.2.3.3 - Efficacy Trial - 2005-LB-GH-TOM-01 - Greenhouse Tomatoes, DACO: 10.2.3.3
- 1374753 2006, 10.2.3.3 - Efficacy Trial - 2006-LB-GH-TOM-01 - Greenhouse Tomatoes, DACO: 10.2.3.3
- 1374754 2006, 10.2.3.3 - Efficacy Trial - 2006-LB-GH-TOM-02 - Greenhouse Tomatoes, DACO: 10.2.3.3
- 1374755 2005, 10.2.3.3 - Efficacy Trial - 2005-DM-GH-L-01 - Greenhouse Lettuce, DACO: 10.2.3.3
- 1374756 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-POT-01 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374757 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-POT-02 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374758 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-POT-03 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374759 2004, 10.2.3.3 - Efficacy Trial - 2003-LB-POT-01 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374760 2004, 10.2.3.3 - Efficacy Trial - 2004-LB-POT-01 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374761 2004, 10.2.3.3 - Efficacy Trial - 2004-LB-POT-02 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374762 2006, 10.2.3.3 - Efficacy Trial - 2005-LB-POT-01 - Root and Tuber Vegetables, DACO: 10.2.3.3
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- 1374763 2005, 10.2.3.3 - Efficacy Trial - 2005-LB-POT-02 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374764 2005, 10.2.3.3 - Efficacy Trial - 2005-LB-POT-03 - Root and Tuber Vegetables, DACO: 10.2.3.3
- 1374765 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-01 - Tomatoes, DACO: 10.2.3.3
- 1374766 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-02 - Tomatoes, DACO: 10.2.3.3
- 1374767 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-03 - Tomatoes, DACO: 10.2.3.3
- 1374768 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-04 - Tomatoes, DACO: 10.2.3.3
- 1374769 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-05 - Tomatoes, DACO: 10.2.3.3
- 1374770 2002, 10.2.3.3 - Efficacy Trial - 2002-LB-TOM-06 - Tomatoes, DACO: 10.2.3.3
- 1374771 2004, 10.2.3.3 - Efficacy Trial - 2003-LB-TOM-01 - Tomatoes, DACO: 10.2.3.3
- 1374772 2004, 10.2.3.3 - Efficacy Trial - 2004-LB-TOM-01 - Tomatoes, DACO: 10.2.3.3
- 1374773 2006, 10.2.3.3 - Efficacy Trial - 2006-LB-TOM-01 - Tomatoes, DACO: 10.2.3.3
- 1374774 2004, 10.2.3.3 - Efficacy Trial - 2004-CT-GH-TOM-01 - Greenhouse - Phytotoxicity, DACO: 10.2.3.3
- 1374775 2004, 10.2.3.3 - Efficacy Trial - 2005-CT-GH-CU-01 - Greenhouse Phytotoxicity, DACO: 10.2.3.3
- 1374776 2005, 10.2.3.3 - Efficacy Trial - 2005-CT-GH-TOM-01 - Greenhouse Phytotoxicity, DACO: 10.2.3.3
- 1374777 2005, 10.2.3.3 - Efficacy Trial - 2005-CT-GH-TOM-02 - Greenhouse Phytotoxicity, DACO: 10.2.3.3
- 1374778 2005, 10.2.3.3 - Efficacy Trial - 2005-CT-GH-TOM-03 - Greenhouse - Phytotoxicity, DACO: 10.2.3.3
- 1374779 2005, 10.2.3.3 - Efficacy Trial - 2005-CT-GH-TOM-04 - Greenhouse - Phytotoxicity, DACO: 10.2.3.3

